General Comment on the Process for Applying for the Increase to the FTE caps Under Section 422

Comment: Several commenters complimented CMS on the proposed process for applying for the section 422 increase to the FTE caps. One commenter stated: "[the commenter] appreciates that CMS had a very difficult task in determining which teaching hospitals that wish to increase their FTE resident caps are "deserving" of such an increase. The combination of very specific statutory language (for example, the hospital priority ordering) on the one hand and the discretion granted to the agency on the other hand, along with the short timeframe for implementation, clearly created significant challenges, and [the commenter] applauds the thought and effort that went into developing the criteria, and CMS's attempt to develop an 'objective process.'"

On the other hand, several commenters believed the proposed administrative process for hospitals to receive cap increases under section 422 was complex and burdensome. One commenter believed that CMS should withdraw the proposals on the increases under section 422 to "reconsider its position on this issue." Another commenter stated that the proposed process is "so complicated and burdensome that most hospital systems will not participate in the process. Only large university affiliated residency programs have personnel to pursue this process of reallocation of [the estimated] pool of resident numbers." In addition, another commenter believed the proposed process for applying for the increase under section 422 is "exceedingly complex and convoluted." This commenter urged CMS to "take pains to minimize the complexity of the

redistribution process so as to ensure that all eligible hospitals are able to quickly assess the opportunities."

Response: We appreciate the consideration from the commenters on the difficult nature of implementing section 1886(h)(7)(B) of the Act. We also recognize the complexity in the application process. We believe the "complexity" is largely a function of CMS's need to meet the statutory requirements for prioritizing the requests and for assuring that the requesting hospital has demonstrated the likelihood of filling the requested slots within 3 years. We hope that the complexity does not deter hospitals from availing themselves of the opportunity to apply for an increase to their FTE resident caps under section 422 of the MMA.

Comments on the Proposed Demonstrated Likelihood Criteria

Comment: We received a variety of comments from the public on the proposed Demonstrated Likelihood requirements, as described in the May 18, 2004 proposed rule. Some of the commenters were supportive of the proposals. One commenter stated: "[w]e believe it serves no worthy programmatic or policy purpose for CMS to grant increases in resident FTE caps absent clear and convincing evidence that a hospital making the application is an institution with a proven track record of training residents in an environment in which physicians-in-training wish to be educated." Another commenter "wholeheartedly" complimented CMS for proposing, as a prerequisite to a hospital's consideration to receive an FTE resident cap increase under section 422, "that each hospital meet at least one of the four criteria" proposed.

On the other end of the spectrum, many commenters requested that there be flexibility in the requirements for hospitals to "demonstrate the likelihood". For instance, several commenters suggested that it is unnecessary and burdensome for hospitals to submit accreditation letters in the Demonstrated Likelihood Criteria 1 through 4. One commenter suggested that hospitals that seek increases under section 422 be permitted to submit to CMS a "narrative explaining their need and use of the additional slots," as an option available to demonstrate likelihood. This commenter also suggested that other types of documentation should be acceptable to CMS for a hospital to demonstrate the likelihood. The commenter suggested "minutes from internal management, graduate medical education, or board meetings, internal correspondence to the designated institutional office (DIO), or other forms of documentation that demonstrate the institution is seriously discussing initiating new programs."

Response: We understand that the demonstrated likelihood criteria may be difficult to meet for some hospitals that wish to apply for an increase to their FTE resident caps. By proposing multiple options within each Demonstrated Likelihood Criterion, we hoped to provide flexibility to hospitals, to allow several options for hospitals to meet this preliminary eligibility criterion to be considered to receive an increase in its FTE resident cap, but to do so in as an objective and documentable way as possible. For this reason, as a first level test, to allow a hospital to demonstrate that it would be very likely to use any increase in its FTE resident cap for a program that is, or will likely soon be approved, we proposed to rely on accreditation letters from the appropriate approving bodies for the residency programs at the applicant hospitals. We

regret that some commenters believe this would be burdensome. However, the commenters' alternative proposal to allow a hospital to submit a "narrative explaining their need and use of additional slots" is, by its nature, subjective and not easily verifiable, which is exactly what CMS sought to avoid in developing the application process. To address the other suggestions from the commenter regarding the reliance on "minutes from internal management…" and other types of documentation to support the Demonstrated Likelihood Criterion, we considered each of the suggestions. It appears to us that each of the alternative types of documentation proposed by the commenters would not objectively demonstrate that the hospitals are seriously planning to start a new program or expand an existing program. Thus, we do not agree that these other types of documentation would *demonstrate the likelihood* that the hospital would fill any additional FTE slots if its application to receive an increase in its FTE resident cap was approved. We believe that our demonstrated likelihood criteria, as finalized in this rule and explained further below, provide an appropriate balance between the flexibility desired by hospitals seeking to meet this eligibility criterion and the objectivity required for CMS to be assured that the criterion is meaningful and measurable.

Comment: We received one comment on the option under proposed Demonstrated Likelihood Criterion 1, for hospitals to demonstrate they can fill the slots of a new program that is established on or after July 1, 2005, that states:

"● Application for approval of the new residency program has been submitted to the ACGME or the AOA by December 1, 2004. **(Copy attached.)**"

The commenter states that, although the requirement for such documentation "may be reasonable," the commenter believes the timeframe established by CMS "is simply not feasible." The commenter believes the December 1, 2004 date "would require a hospital to apply to ACGME or AOA prior to knowing whether it will be granted the additional slots." The commenter requests that CMS reevaluate the timeframe associated with this option.

Response: We understand the commenter's concern about the uncertainty of an applicant hospital as to whether it would receive an increase in its FTE resident caps when it applies by December 1, 2004 for accreditation for a new program(s). However, we deliberately set up this criterion so that CMS is able to determine, at the time we evaluate hospital applications for increases in FTE resident caps, which hospitals are able to *demonstrate the likelihood* of filling the slots of the new program. Applications for new programs that will be submitted to the ACGME or the AOA *after* December 1, 2004 (which is the deadline for most hospital applications for increases in FTE resident caps) are not at all helpful to CMS for determining which hospitals can demonstrate the likelihood, since CMS will need to make FTE cap increase determinations under section 422 effective July 1, 2005. For this reason, we have decided to maintain the originally proposed date requirements associated with this option under this Demonstrated Likelihood Criterion 1.

Comment: We received many comments on Demonstrated Likelihood Criteria 1 and 2, concerning the ability of the hospital to demonstrate that it will be likely to fill the requested slots. Specifically, these commenters were concerned with the option under

each criterion that "if the hospital is [expanding an existing/establishing a new] residency program in a particular specialty, [the hospital must] submit documentation indicating that the specialty has a resident fill rate nationally, across all hospitals, of at least 95 percent."

One commenter, representing a particular specialty in medicine, disliked the option of a national fill rate of 95 percent in the specialty, stating that the commenter preferred the option in the Demonstrated Likelihood Criteria 1 and 2 to use a hospital-specific fill rate to demonstrate that the hospital will likely fill the number of slots requested: "if the hospital has other previously established programs, submit documentation that each of the hospital's existing residency programs had a resident fill rate of at least 95 percent in each of program years 2001 through 2003."

Another commenter requested that if the national fill rate option is retained by CMS, that the threshold percentage of 95 percent should be reduced.

Several commenters asked CMS to define "fill rate," as used in the Demonstrated Likelihood Criteria. They noted that the term fill rate is often confused with the "match fill rate," and that not all resident positions are filled through a match process. However, these commenters felt that use of a clearly defined national fill rate is an appropriate measure. One commenter stated that, by "fill rate," the commenter believed we were referring to resident match data. Several commenters requested that we also include in our definition that "national fill rate" refers to the fill rate as of July 1st of each year.

One commenter was opposed to the use of the national fill rate as an indication that a program is likely to fill new FTE resident slots awarded pursuant to

section 1886(h)(7)(B) of the Act, because it believed this measure would be misleading. The commenter noted that hospitals may choose to conduct a training program with fewer residents than allowed by their approved accredited slots and that "the fact that all of the accredited resident slots are not utilized may have little bearing on the ability of the institution to attract residents to its residency programs."

Response: Section 1886(h)(7)(B)(ii) of the Act specifies that in determining which hospitals will receive the increases in their FTE resident caps, we are required to take into account the demonstrated likelihood that the hospital would fill the position(s) within the first three cost reporting periods beginning on or after July 1, 2005. In order to make this determination, we proposed four objective criteria, at least one of which must be met, in order demonstrate a likelihood of filling the positions within the first three cost reporting periods beginning on or after July 1, 2005. Two of the criteria are for hospitals that intend to use the additional FTE resident cap slots to establish a *new* residency program(s) on or after July 1, 2005, or to expand an *existing* residency program on or after July 1, 2005. It is especially difficult to develop criteria that are administratively feasible, objective, and verifiable in order to demonstrate the likelihood that a hospital's future plans will be implemented. In an effort to design criteria that would objectively demonstrate that hospitals would fill additional residency positions associated with a new or expanded program(s), we proposed several criteria, one of which is that the specialty for which the hospital intends either to start a new program or to expand an existing program has a resident fill rate nationally, across all hospitals that offer the program, of at least 95 percent. We believe new or expanded programs in a specialty that is 95 percent

full nationally, across all hospitals, would be a reasonable basis for determining that a hospital has demonstrated the likelihood that it will fill new positions in that specialty.

However, we agree with the commenters that the "national fill rate" should be defined with more accuracy. Furthermore, in light of the comments we received regarding "fill rate" and "residency match," we agree that it is necessary to more explicitly distinguish between "residency match" and "resident fill rate" for the purpose of determining that there is a demonstrated likelihood a hospital will fill the slots if granted an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act.

For purposes of the application for the increase to the FTE caps under section 422, we are defining "national fill rate" for each academic year, as the number of residents training in a program nationally as compared to the number of accredited slots in that program as of June 30 of that year. This information is available from the ACGME and the AOA. Furthermore, we are requiring that, for the purposes of an application for an increase to a hospital's FTE resident cap under section 1886(h)(7)(B) of the Act, a hospital must use the "fill rate" for the most recent academic year for which data is available.

We agree with the commenter that hospitals may train fewer residents than the number of available accredited slots in their approved programs due to reasons other than an inability to fill those slots. Accordingly, we agree that the proposed 95 percent threshold national fill rate for demonstrating the likelihood of filling FTE resident slots in a new or expanded program may not take into account some of the reasons (other than an inability to fill the positions) that a program may be training fewer residents than it is

accredited to train. Therefore, as suggested by the commenter, we are lowering the fill rate "threshold" to 85 percent. We believe that this lower rate will reasonably identify those programs that are likely to fill FTE resident positions in newly approved or expanded programs (while providing some latitude to account for other factors, beside ability to fill accredited slots, that affect the national fill rate), and to fully utilize an increase in FTE resident cap slots that may be available under section 1886(h)(7)(B) of the Act. By establishing a threshold of 85 percent, we believe, based on the most current data available from both the ACGME and AOA, that we will have identified approximately 30 percent of the currently approved programs, as meeting this criterion. Accordingly, we believe the revised threshold will better identify those programs as having a demonstrated likelihood of actually filling the new or expanded programs.

Furthermore, based upon our additional research in response to public comments, we believe that a national fill rate is not necessarily the only indicator of the ability of hospitals to fill residency positions in its MSA or State. There may be characteristics particular to a region, such as population density, variety of practice settings, or access to technology or procedures that may allow a specified area to have a fill rate in a specific program that exceeds the program's national fill rate. Therefore, we are expanding the ways that a hospital may satisfy the "fill rate" criterion. In this final rule, we are specifying that a hospital may demonstrate the likelihood of filling FTE resident positions associated with a possible increase in its FTE resident cap under section 422 by documenting that any of the following applies to the new program or to an expansion of an existing program:

- The specialty program has a resident fill rate nationally, across all hospitals, of at least 85 percent.
- The specialty program has a resident fill rate within the state in which the hospital is located of at least 85 percent.
- If the hospital is located within an MSA, the specialty program has a resident fill rate within the MSA of at least 85 percent.

We are amending the proposed CMS Evaluation Form part A1(2) and part A2(2) to include the following language: "The specialty program has a resident fill rate either nationally, or within the state or the MSA in which the hospital is located, of at least 85 percent." For the purposes of demonstrating the likelihood of filling FTE resident positions for purposes of section 1886(h)(7)(B)(ii) of the Act, "fill rate" means, for the most recent academic year for which data is available, the number of residents training in a program compared to the number of accredited slots in that program as of June 30 of that year.

As we stated in the proposed rule, we believe that, of all the medical specialties, geriatrics is the one specialty that is devoted primarily to the care of Medicare beneficiaries. In addition, we note that encouraging residency training in geriatrics in the context of Medicare payments for direct GME and IME is consistent with Congressional intent as expressed, among other places, in section 712 of Public Law 108-173. As such, we are giving special consideration to geriatric programs to meet the "fill rate" criterion for demonstrating the likelihood of filling FTE resident slots under section 422. Geriatrics is not a separately approved training program; rather, it is a subspecialty of

another specialty program. For example, there is a geriatrics subspecialty of family practice. In this final rule, for the purposes of meeting the 85 percent fill rate criterion, we will allow hospitals that are starting a new geriatrics program or expanding an existing geriatric program to use the fill rate associated with the overall specialty program (rather than the fill rate for the geriatric subspecialty) to meet this demonstrated likelihood criterion.

The proposed Demonstrated Likelihood Criterion 3 (as finalized in this rule) allows hospitals that are already training a number of FTE residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both, to meet the demonstrated likelihood requirement. In order to document that it meets this criterion a hospital must submit copies of the 2004 "residency match" information concerning the number of residents the hospital has in an existing program. For purposes of the application of this demonstrated likelihood criterion, we are defining "residency match" as a national process administered by the National Residency Matching Program (NRMP), the San Francisco Matching Program, the American Osteopathic Association Residency Match Program, or the Urology Matching Program, by which applicants to approved medical residency programs are paired with programs on the basis of preferences expressed by both the applicants and the program directors.

The proposed Demonstrated Likelihood Criterion 1 and Demonstrated Likelihood Criterion 2 (also finalized in this rule) also allow a hospital to demonstrate the likelihood of filling the requested slots by demonstrating that the hospital's existing residency programs had a "resident fill rate" of at least 95 percent in each of program years 2001

through 2003. For the purpose of fulfilling these demonstrated likelihood criteria, we are defining "resident fill rate" to mean, for the most recent academic year for which data is available, the number of residents training in each program at a hospital as compared to the number of accredited slots in each program at that hospital as of June 30 of that year. Furthermore, for the reasons stated above, we are lowering the threshold percentage from 95 percent to 85 percent.

Comment: One commenter questioned the need for the option under Demonstrated Likelihood Criteria 1 and 2 of a hospital providing the resident fill rate for its other residency programs. The commenter believes that a hospital's ability to fill the slots of a new program, for example, "bears no relationship" to the fill rate of the hospital's other program(s).

Response: We disagree with the commenter's contention that the fill rates in the hospital's existing residency programs "bear no relationship" to the hospital's ability to fill slots in other programs. We continue to believe that the hospital's fill rate in all of its programs is a meaningful indicator to "demonstrate the likelihood" that a hospital will fill slots in a new program or an expansion of an existing program for purposes of section 422 of Public Law 108-173. We believe the hospital's location, faculty, patient base, and reputation all have a direct bearing on the overall ability of a hospital to fill either its new or its existing residency positions and that this criterion provides an objective method of demonstrating the likelihood that the hospital will fill residency positions for purposes of section 422. As such, we continue to believe that it is appropriate to include the fill rates of existing programs as one of the methods by which a

hospital may demonstrate the likelihood of filling FTE residency positions for purposes of section 422. Of course, where a hospital's fill rates fall below the acceptable threshold, the hospital may still demonstrate a likelihood of filling the requested slots based on the fill rate, either nationally, within the MSA, or within the State that the hospital is located, for that program.

Comment: We received one comment on the option under the proposed Demonstrated Likelihood Criterion 2 that states that the hospital may demonstrate the likelihood of filling FTE resident slots by demonstrating that:

- Hospital has employment contracts with the residents who are or will be participating in the expanded program (resident specific information may be redacted) and employment contracts with the residents participating in the program prior to the expansion of the program. **(Copy of the cover page of both documents attached.)**

Similar documentation requirements were proposed under Demonstrated Likelihood Criterion 1 for new programs.

The commenter believed that it is "onerous and unnecessary" for CMS to require hospitals to submit resident employment contracts. The commenter also believed that hospitals would be unable to provide contract information by December 1, 2004 (the application deadline for most hospitals to request the increase to the FTE caps under section 422) since residents who will be training in a program that starts July 1, 2005 will not be identified until Spring 2005.

Response: We agree with the commenter that residency match results from the National Residency Match Program (NRMP) for the academic year beginning July 1, 2005 will not be available until March 2005. Similarly, residency match results from the American Osteopathic Association (AOA) for the academic year beginning July 1, 2005 will not be available until February 2005. Since employment contracts are not signed until after this date, we agree that hospitals will be unable to provide copies of the cover page of residents' employment contracts as a method of demonstrating the likelihood that the hospital will fill residency positions for purposes of an increase in its FTE resident caps by the December 1, 2004 application deadline. Therefore, we are removing this option from the final rule. Under the final rule, hospitals will be required to demonstrate the likelihood of filling the requested slots by either of the two other methods--

- If the hospital has other previously established programs, submit documentation that each of the hospital's existing residency programs had a resident fill rate of at least 85 percent in each of program years 2001 through 2003; or
- If the hospital is establishing or expanding a program in a particular specialty, submit documentation indicating that the specialty has a resident fill rate either nationally, or within the state, or MSA in which the hospital is located, of at least 85 percent.

Comment: One commenter had concerns with the option under Demonstrated Likelihood Criterion 2 that states:

"• The National Residency Match Program or the American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. **(Documentation attached.)**"

The commenter stated that if "CMS will recognize only program expansions that take effect on or after July 1, 2005, for hospitals that utilize the NRMP, their resident match information is not required until early 2005—after the December 2005 application deadline." The commenter also questioned how a hospital under this option would demonstrate that the matching program "will be accepting" the hospital's match participation with the expanded resident slots.

Response: Under the proposed Demonstrated Likelihood Criterion 2, a hospital may demonstrate that it intends to expand an existing program by documenting that either the National Residency Match Program or the AOA Residency Match Program have accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. We agree with the commenter that resident match information for the academic year beginning July 1, 2005 is not due to the NRMP until February 2005. As such, hospitals will not be able to document that the NRMP has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots by the December 1, 2004 application deadline. Therefore, we are removing this option for hospitals to demonstrate that they intend to expand an existing program

from the final rule for NRMP programs. Programs utilizing the NRMP will be required to demonstrate the intent to expand an existing program by either of the two other methods:

- Document that the appropriate accrediting body (the ACGME or the AOA) has approved the hospital's expansion of the number of FTE residents in the program.
- If expanding an allopathic program, submit a copy of the hospital's institutional review document or program information form for the expansion of the existing residency program.

We note that the listing of programs participating in the AOA Match Program will be available on the National Matching Services website as of November 1, 2004. Therefore, programs utilizing the AOA Match Program may, in addition to the two options listed above, demonstrate the intent to expand an existing program by documenting that the AOA has accepted the hospital's participation in the match program by the December 1, 2004 application deadline. Therefore, this method of demonstrating the hospital's intent to expand an existing program will be adopted as final for programs participating in the AOA Match Program.

Comment: One commenter expressed concern about Demonstrated Likelihood Criterion 1 and the option to include information regarding the application for the approval of the new program. The commenter mentioned that, in many cases, there are letters of intent that are sent to the accrediting body a year or two prior to submission of the application for accreditation. This commenter states that "since in many instances, the institution cannot increase its slots, or begin a new program, without the Medicare

reimbursement, many programs would be in the situation of needing a full-blown application to the accrediting body, before they know if they will be awarded new positions by a raising of their cap. It makes sense to allow this earlier letter of intent, to allow those institutions the ability to start a new program, if they receive the increase in paid positions under this program."

Response: We believe that a letter of intent does not meet the standard of "demonstrated likelihood of the hospital filling the positions." It would only seem to portend hopeful intention on the part of the hospital, rather than a commitment. Therefore, we are not adopting the commenter's suggestion of a letter of intent as source of documentation.

Comment: One commenter was concerned about the accreditation options under Demonstrated Likelihood Criteria 1 and 2. For example, the option under Demonstrated Likelihood Criterion 2, states--

"● The appropriate accrediting body (the ACGME or the AOA) has approved the hospital's expansion of the number of FTE residents in the program. **(Documentation attached.)**"

One commenter believed that this option should recognize and accommodate hospitals that are planning to expand a residency program(s), but have already received ACGME accreditation.

Response: We understand that in many instances, hospitals receive accreditation from the approving body before training residents in the expanded program (which can be a period of a year or more after receiving the accreditation). We believe that our

proposed language above already accommodates the idea of hospitals receiving accreditation for the expanded number of FTE slots.

Comment: We received two comments on the option to document, for proposed Demonstrated Likelihood Criteria 1 and 2, that the appropriate accrediting body has approved the hospital's new program or expansion of the number of FTE residents in the program. One commenter notes that an application for residency program expansion "is a complex, extensive document that cannot be prepared in the roughly six-month time frame from this notice of proposed rule making to the December 1st deadline. A request for expansion often triggers an 'early' site visit by the specialty Residency Review Committee (RRC) and site visitor schedules are booked six to 12 months in advance." Another commenter notes that the proposed date by which a hospital would be required to document the approval of the accrediting body would mean that the hospital would have to file an application with the ACGME/AOA "before knowing whether it will receive the additional slots necessary to fund [the] new or expanded program. We urge CMS to reconsider this timeframe to allow hospitals to receive slots contingent on receiving [AOA/ACGME] approval."

Response: CMS understands that the applications for approval of new/expanded programs for the ACGME and the AOA are extensive documents that *demonstrate* a commitment on behalf of the hospitals to establish/expand a program. For this reason, we believed applications for approval are good sources of documentation to demonstrate the likelihood for purposes of the section 422 increase. We recognize that applying for program approval is a lengthy process that takes a significant period of time before

approval is given by the ACGME/AOA. The commenter is correct in believing that it would be unlikely that hospitals would have enough time to apply for program approval from the ACGME/AOA (either for expansion or new program accreditation) within the timeframe set up by CMS for applying for the section 422 caps. However we have chosen December 1, 2004 as the date on which to show the approval, (since, as explained earlier, we intend to begin the allocation of the section 422 cap process in December)—and need to know at that time whether hospitals can *demonstrate the likelihood* of filling the slots. Under this criterion, we believe we will enable hospitals that were *already contemplating* new/expanded program approval from the ACGME/AOA to be considered to receive an increase in their FTE resident caps under section 422. Under another criterion, we have addressed the situation where a hospital was already training residents above its 1996 FTE caps, *before* CMS proposed and finalized the application process implementing section 422. We do not believe a hospital that is merely contemplating the future possibility that it will train a number of residents in excess of its FTE resident caps can demonstrate the likelihood that it will fill additional positions within the timeframe for our decision process under section 1886(h)(7)(B) of the Act.

Therefore, we are not making additional changes to this option under Demonstrated Likelihood Criteria 1 or 2.

Comment: We received one general comment that the "single best piece of evidence" for a hospital to "demonstrate the likelihood" of filling the slots under section 422 is the fact that a hospital is already training a number of residents in excess of its FTE caps.

Response: We agree with the commenter that hospitals are able to fulfill the demonstrated likelihood requirement by documenting to CMS that they are training a number of FTE residents that exceeds their FTE cap(s) in the manner described in this final rule.

Comment: One commenter asked for flexibility in the choices under the proposed Demonstrated Likelihood Criteria 1 and 2. Specifically, the commenter pointed out that sections A1(1) and (2) and A2(1) and (2) of both criteria offer options in order to fulfill the demonstrated likelihood requirement; and that CMS proposed that the hospital be able to meet "one of the following" choices under each requirement. The commenter suggested that CMS add language that directs the hospital applicant to "check all that apply" at the beginning of A1(1) and (2) and A2(1) and (2) of the criteria.

Response: We understand that a particular hospital applicant may be able to meet more than one of the choices under A1(1) and (2) and A2(1) and (2).

For instance, it is possible that, in order to meet A1(1), a hospital may have written correspondence from the ACGME or AOA acknowledging receipt of the application for a new residency program, but may also have the actual application for the approval of the new program. We would not ask hospitals to provide any more documentation than is necessary under each of the options under A1(1) that is chosen by the applicant hospital; however, to provide hospitals with additional flexibility, if an applicant hospital would like to choose more than one of the options under A1(1) and (2) and A2 (1) and (2), we are adding language at the beginning of each of A1(1) and (2) and

A2 (1) and (2) of Demonstrated Likelihood Criteria 1 and 2 that says "Check at least one of the following, if applicable".

Comment: One commenter stated that there are a few residency programs in a particular specialty that received accreditation from the ACGME in 2003, for which the hospitals sponsoring these programs are training their first class of PG-1 residents in July 2004. The commenter urged CMS to revise the proposed Demonstrated Likelihood Criterion 1 that relates to establishing a new residency program on or after July 1, 2005. Specifically, the commenter stated that the new programs described were accredited after January 1, 2002, "…and can more appropriately demonstrate ability to fill to the full complement of residents in the next three cost reporting years, except that those years will be 2004-2007, rather than 2005-2008."

Response: Section 1886(h)(7)(B)(ii) of the Act, as modified by section 422 of Pub. L. 108-173, specifies that: "[i]n determining for which hospitals the increase in the otherwise applicable resident limit is provided…the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005." (Emphasis added.) We provided several methods for hospitals to be able to demonstrate to CMS under the proposed Demonstrated Likelihood Criterion 1 that they can fill the slots by showing to CMS that they are establishing a new residency program on or after July 1, 2005. We believe hospitals that establish new residency programs before July 1, 2005, could possibly meet Demonstrated Likelihood Criterion 2, relating to a hospital that is expanding an existing residency program on or after July 1, 2005. From the perspective of applying for the cap

increase under section 422, the new program that starts training residents in 2004 is an "existing residency program" if established before July 1, 2005, and it is "expanding" if that program is increasing in the number of FTE residents in the first three cost reporting periods beginning on or after July 1, 2005.

Comment: We received one comment asking whether a hospital that applies for an increase in its FTE resident cap under section 422 and establishes a newly accredited program that starts in 2006 would be eligible to receive "the full complement of accredited positions, or only the first and second year (for example, 12 of 18 accredited slots) under these [proposed] regulations." Similarly, another commenter described the situation of a hospital that establishes a new residency program that, because of the length of the accreditation process and a relatively long match period, will be unable to accept its first class of PGY-1 residents until July 1, 2006. The commenter urged CMS to clarify whether a new program like this will be able to receive a full complement of residents for the three years beginning July 1, 2006.

Response: Assuming the applicant hospital can demonstrate the likelihood that it will fill the slots relating to a possible increase in its FTE resident caps under section 422, as provided in the criteria on the CMS Evaluation Form, and finalized in this final rule, the applicant hospital may request on its application an increase of up to 25 FTE residents for direct GME and IME. However, if the applicant hospital does not demonstrate the likelihood that it will fill any FTE slots as claimed for programs described by the hospital on the CMS Evaluation Form(s) at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2005, the hospital will not be eligible to

apply for the increase to the FTE caps under section 422. We do not believe our proposed Demonstrate Likelihood Criterion 1 reflects this point and, accordingly, are making the following changes with this final rule:

"A1: Demonstrated Likelihood Criterion 1. The hospital intends to use the additional FTEs to establish a new residency program (listed above) on or after July 1, 2005 (that is, a newly approved program that begins training residents at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2005)."

Comment: One commenter stated that a hospital may meet the demonstrated likelihood requirement by documenting that it is establishing a new program or expanding an existing program, on or after July 1, 2005. The commenter asked whether the hospital is then limited to submitting a CMS Evaluation Form only for that program: The commenter suggested that if the answer is yes and CMS ultimately grants additional slots to the hospital based on the needs for that program, it seems unclear whether CMS would take the view that the additional cap slots could only be used for the program listed in the application.

Response: As we have stated in this final rule, each application by a hospital must be program specific. That is, the hospital must complete a separate CMS Evaluation Form for each program and demonstrate the likelihood of filling the slots in each program. However, increases in hospital's FTE resident caps under section 422 for direct GME and IME, once granted to a hospital, are no longer program specific. Rather, the caps are applied to any residents the hospital trains in excess of its otherwise

applicable FTE cap(s) (Which could include the hospital's 1996 caps, subject to permanent adjustments for new programs or reductions under section 1886(h)(7)(A) of the Act.).

Comment: One commenter believed that the proposed rule omitted the documentation requirement in the Demonstrated Likelihood Criteria for new programs and expansions of existing programs for "what should be key"; that is, that the applicant hospital requesting the additional slots for the new/expansion program would have already exceeded its 1996 FTE caps in previous years.

Response: While we believe a majority of those hospitals applying for the increase to the FTE caps for new programs and expansions of existing programs will already be training a number of residents that exceeds their FTE caps, we do not believe this circumstance is a necessary condition for all of the hospitals that apply. For example, a hospital whose FTE resident cap is reduced under section 1886(h)(7)(A) of the Act may have been planning to establish a new program in July 2006 that would have put the hospital's FTE resident count above its 1996 FTE cap at that time. Therefore, we see no reason to require that, at the time of the hospital's application, the hospital necessarily either exceed or be at its FTE cap, in order to meet the demonstrated likelihood requirement. Thus, we are not adopting the commenter's proposal to require hospitals to be training a number of residents that is at or over their FTE caps in order to meet the Demonstrated Likelihood Criteria 1 or 2.

We note that we will be aware if an applicant hospital is training residents in excess of its FTE caps, even if the hospital checks off Demonstrated Likelihood

Criteria 1 or 2 because, as part of the hospital's application for the section 422 increase to the caps, we proposed that the hospital must provide both the FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report (69 FR 28301). We are finalizing this application requirement with this final rule. (We have included a summary of the application requirements at the end of this section of this preamble).

Comment: One commenter indicated that there is a lack of clarity with proposed Demonstrated Likelihood Criterion 1 by stating that the precise documentation requirements differ between what is discussed in the preamble and what is proposed on the CMS Evaluation Form. The commenter believed that the submission of a new program application should not be required under second option under (1).

Response: It may have appeared to the commenter that the documentation requirements in the preamble language and the proposed CMS Evaluation Form for Demonstrated Likelihood Criterion 1 were different, because the preamble language states that the hospital must, in conjunction with every available option, submit a copy of the application for approval for the residency program "to the ACGME or the AOA by December 1, 2004", whereas the proposed CMS Evaluation Form asks for a copy of the new program application for only one of the options. We would like to clarify that the documentation required for (1) under A1 is limited to what is requested on the CMS Evaluation Form, as finalized in this final rule. We are not requiring a copy of the new program application as part of the documentation associated with the second option under (1). In the second option, we are only requiring a copy of the institutional review

document or program information form concerning the new program that hospitals include as part of their applications for approval.

Comment: Several commenters suggested that CMS include options under the demonstrated likelihood criteria that take into account programs that seek certification from the American Board of Medical Specialties ("ABMS"). For example, under Demonstrated Likelihood Criterion 1, under the first requirement, the hospital is given choices for documenting its application for new program accreditation from the ACGME or the AOA. The commenters asked what hospitals should do to demonstrate likelihood if the programs for which the hospitals are requesting cap increases for under section 422 are certified by the ABMS.

Response: We agree with the commenter that there are certain residency programs that are certified by the ABMS and that do not require certification by the ACGME or AOA. Our regulations currently recognize these programs as approved programs for purposes of direct GME and IME payments. Therefore, we believe it is appropriate to include the ABMS as a certifying organization for the purposes of Demonstrated Likelihood Criterion 1 and Demonstrated Likelihood Criterion 2. We are adding the following language to the CMS Evaluation Form at A1(1):

- "Application for approval of the new residency program has been submitted to the ACGME, AOA, or the ABMS by December 1, 2004. (**Copy Attached.**)"
- "The hospital has received written correspondence from the ACGME, AOA, or ABMS acknowledging receipt of the new program, or other types of

communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). (**Copy Attached**.)"

We are also adding the following language to the CMS Evaluation Form at A2(1): "The appropriate accrediting body (the ACGME, AOA, or ABMS) has approved the hospital's expansion of the number of FTE residents in the program. (**Documentation attached**.)"

Comment: We received several comments suggesting that the requirements under proposed Demonstrated Likelihood Criterion 3 are burdensome. Proposed Demonstrated Likelihood Criterion 3 states--

"• A3: Demonstrated Likelihood Criterion 3. Hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both. **(Copies of EACH of the following attached.)**

● Copies of the most recent as-submitted Medicare cost reports documenting on Worksheet E, Part A and Worksheet E3, Part IV the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

● Copies of the 2004 residency match information concerning the number of residents the hospital intends to have in its existing programs.

● Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME."

The commenters questioned why all of the documentation requirements are necessary to demonstrate that the hospital is already exceeding its FTE cap at the time the hospital is applying for an increase in its FTE resident caps. Specifically, one commenter suggested that the most obvious way for CMS to get the information on whether the hospital is counting residents above its FTE caps is the Medicare cost report. However, the commenter believed that "[i]n many instances an FTE request [to count a number of residents that is] greater than the cap is not entered into the cost report due to the fact that it is futile to do so as the reimbursement will not change. However, Intern and Resident Information Survey (IRIS) data, contract cover pages, resident schedules, etc. can all be used to demonstrate that the actual resident FTE that could be counted for IME and DME purposes is greater than the cap allows. This commenter proposed that CMS allow hospitals to use these alternative sources of information." This commenter believed that the second option, to use 2004 residency match information, only shows an intent to fill slots, not that the slots have actually been filled. The commenter believed that it would be more accurate to look at the hospital's 2004 fill rate, which is available after July 1, 2004. Finally, this commenter had concerns with the third option under this criterion—to look at accreditation letters on all the hospital's programs. The commenter believed that the Residency Review Committee (RRC) for family practice does not accredit a program with a specific number, and encouraged CMS to change this requirement because it "does not fit the configuration of family practice residency accreditation."

Response: We agree with the comment that "the most obvious way" for CMS to determine whether a hospital is training FTE residents in excess of its FTE cap is to look at Medicare cost report information. Regarding the comment that some hospitals do not show on the cost report that they are over their FTE caps because the excess FTE residents would have no effect on Medicare direct GME and IME payments, We do not agree that hospitals should not be reporting all the FTE residents that the hospital is training. According to the regulations under §413.86(f) (as redesignated as §413.78), hospitals must report the actual total number of FTE residents. The total number of residents the hospital trained (even if it is in excess of the cap(s)) is actually used in determining direct GME and IME payments. For example, if the number of FTE residents exceeds the hospital's FTE cap for direct GME, if the hospital has two different per resident amounts (PRAs) for primary care and non-primary care, we prorate the reduction in the allowable number of FTE residents to bring the number of primary care and non-primary care FTEs to the hospital's FTE cap. In addition, we note that representatives of hospitals must attest on the Medicare cost report to the truth and accuracy of the information reported. Thus, it is *required* that hospitals include the total number of FTE residents in their cost reports, even if the hospital, is not allowed to count the residents for purposes of Medicare direct GME and IME payments as a result of application of the FTE resident cap(s).

To respond to the comment concerning the use of IRIS data, we believe that IRIS data is most useful from the perspective of looking back at the past and assuring that hospitals are not submitting duplicate FTE counts; we do not believe IRIS data would be

helpful to determine whether hospitals can “demonstrate the likelihood of filling the positions” in the future. The documentation requirement regarding resident employment contracts is addressed in another comment and response above.

We agree with the commenter that the second documentation requirement, regarding 2004 residency match information for all the programs at the hospital, only shows an intent to fill slots and not that slots have actually been filled. In proposing to require 2004 match information, we sought this information even though it is more relevant to a hospital’s "intent to fill" programs because we believed the information would portend that the hospital would continue to be over its FTE cap on or after July 1, 2005, as the statute requires in the demonstrated likelihood requirement. However, we agree with the commenter, and have decided to offer another option under Demonstrated Likelihood Criterion 3 to allow hospitals to provide fill rate information of all programs at the hospital in 2004, in addition to offering 2004 match information.

Finally, regarding the documentation requirement for the copies of the recent accreditation letters for all of the hospital’s programs, we disagree with the commenter’s suggestion that we intended to match the listed number of resident positions in the accreditation letters with the number of slots claimed on the Medicare cost report. Our purpose in proposing to require accreditation documentation for all programs is so that we could ensure that all the hospital’s programs continue to be accredited, that is, to verify the legitimacy of the applicant hospital’s programs, not to “match” the number on the accreditation letters to the FTE counts on the cost report Worksheets E, Part A and Worksheet E3, Part IV. In addition, we understand that although the ACGME does not

specifically approve a limited number of slots for family practice programs, the number of available slots in each program is determined by the program itself and that data is then reported to the ACGME. Therefore, we are not accepting the commenter's request to excuse hospitals from providing accreditation documentation for family practice programs.

Comment: A number of commenters focused on proposed Demonstrated Likelihood Criterion 4, which states--

"Demonstrated Likelihood Criterion 4. The hospital is applying for the unused FTE resident slots because the hospital is at risk of losing accreditation of a residency training program if the hospital does not increase the number of FTE residents in the program on or after July l, 2005. **(Documentation attached from the appropriate accrediting body of the hospital's risk of lost accreditation as a result of an insufficient number of residents in the program.)**"

Several commenters asked CMS to provide further explanation as to why CMS believed these circumstances merit the addition of this proposed Demonstrated Likelihood Criterion, particularly where the hospital is not training a number of FTE residents in excess of its 1996 FTE cap(s). One commenter asked why hospitals under this criterion do not demonstrate to CMS that the additional cap slots under section 422 are necessary because, increasing the resident slots would otherwise cause the hospitals to exceed their FTE caps. This commenter also believed that, under this criterion, hospitals should demonstrate fill rates as part of the documentation requirements.

Another commenter believed that this criterion does not fit with the requirement that the hospital demonstrate the likelihood that it will fill FTE resident slots "[i]n fact, it says just the opposite– that the program has not been able to fill its slots, and is under a threat of academic consequences. In such cases, we believe it is perhaps better for the program to close, than to waste new slots on a program that has little chance of filling."

Response: When we proposed Demonstrated Likelihood Criterion 4, we were under the impression that there were some hospitals that were training a number of residents below their FTE caps, and were at risk of losing their accreditation if they did not fill their residency program with more slots. However, based upon the public comments we received questioning why the criterion is necessary, and given that we did not receive any comments in support of the criterion, we agree that we should delete Demonstrated Likelihood Criterion 4 from the CMS Evaluation Form in this final rule.

h. Application Process for the Increases in Hospitals' FTE Resident Caps

As stated above, in the May 18, 2004 proposed rule, we proposed an objective decision-making process for determining how hospitals will be prioritized when identifying the hospitals that will receive increases in their FTE resident caps. In order for hospitals to be considered for increases in their FTE resident caps, section 1886(h)(7)(B)(i) of the Act, as added by section 422(a)(3) of Pub. L. 108-173 requires that each "qualifying hospital" submit a "timely application." We proposed that each hospital must submit the following information on its application for an increase in its FTE resident cap:

- The name and Medicare provider number of the hospital.

- The total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME or IME, or both (up to 25 FTEs).

- A completed copy of the CMS Evaluation Form (as described below) for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the Evaluation Form. (For example, if the hospital checks off on the Evaluation Form that the hospital is located in a geographic Health Professions Shortage Area (HPSA), the hospital would include documentation to support that assertion.) A copy of the blank proposed CMS Evaluation Form appears at the end of this section of the preamble.

- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report.

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information in the hospital's application for an increase in its FTE resident cap:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application

prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

We further proposed that any hospital that wishes to receive an increase in its FTE resident cap(s) must submit a copy of its completed application (as described above) to the CMS Central Office and to the CMS Regional Office for the region in which the applicant hospital is located, and that the application must be received on or before December 1, 2004. (The mailing addresses for the CMS offices are indicated at the end of this section of the preamble.) We note that some hospitals' FTE counts will be subject to audit for purposes of section 1886(h)(7)(A) of the Act, and those audits may not be completed by December 1, 2004. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, we proposed to allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for purposes of section 1886(h)(7)(A) of the Act, and that hospital also wishes to apply for an increase in its FTE resident cap(s) available through section 1886(h)(7)(B) of the Act, we proposed that this hospital must submit a completed application to CMS and that the application must be received on or before March 1, 2005. We proposed that all completed applications that are timely received according to the above deadlines will be evaluated by us according to the criteria described under section IV.O.2.i. of this preamble for determining the priority distribution of FTE resident slots. Hospitals that

satisfy at least one of the "demonstrated likelihood" criteria will be further evaluated by the evaluation criteria described below. We proposed that those hospitals that are chosen to receive an increase in their FTE resident caps would be notified by CMS by July 1, 2005.

Comment: Several commenters expressed concerns regarding CMS's overall approach to evaluating the application for the increase to hospitals' FTE caps under section 422. They disagreed with the proposed requirement that, as part of a hospital's application for the increase to the 1996 FTE caps, that is, for the section 422 cap, the hospital must submit a completed copy of the CMS Evaluation Form for each residency program for which the applicant hospital demonstrates a need for the requested increase in the number of FTE residents. One of the commenters stated that "we have fundamental and serious concerns with…an evaluation form that focuses on residency programs, rather than hospital applicants…we think CMS' proposed process could lead, at a minimum, to a de facto situation of program-specific caps, which is contrary to the spirit and intent of the BBA." The commenters were concerned with the possibility that CMS may take the view that the section 422 cap could only be used for the residency programs listed in the hospital's application for the increase. The commenters were also concerned that the evaluation criteria list program-specific criteria on the CMS Evaluation Form (such as a point for using the unused resident slots for establishing a new geriatrics program or for expanding an existing geriatrics program; or for a point for a new program that did not qualify for an adjustment because of the deadlines associated with the BBA). One commenter stated that CMS "should not favor one specialty over

another but should view all specialty programs equally and leave decisions regarding the use of additional residency positions to the hospital." The commenters preferred CMS to focus on the evaluation of the application for the section 422 cap on the hospitals and not on the hospital's residency programs.

Response: We understand the commenters' concerns about the possibility that we have proposed a program-specific section 422 cap. We did not propose and we are not finalizing in this final rule a program-specific section 422 cap. That is, once a hospital receives an increase in its otherwise applicable FTE resident cap effective July 1, 2005, the portion of the cap relating to an increase under section 422 is applied to FTEs in any program that the hospital is training in excess of its 1996 FTE cap (which is subject to any permanent adjustments for new programs and any reductions under section 1886(h)(7)(A) of the Act), regardless of the hospital's program-specific basis for being granted the section 422 cap increase.

We note, however, that hospitals must sign an attestation as part of the hospital's application for the overall increase to the cap under section 422 to certify that the information claimed in the application is true at the time of the application. Thus, if a hospital claims on one of its CMS Evaluation Forms that the hospital is applying for the increase because it plans to use the FTEs because it is training residents from a program or a hospital that closed, and the applicant hospital no longer qualifies for a temporary adjustment to its cap, then at least at the time of the application, the hospital intends to use at least that part of its section 422 cap for this stated purposes (that is documented in the hospital's application). The section 422 caps, as well as the adjusted 1996 FTE caps,

are applied to FTE residents counted by the hospital in all programs in the aggregate, not on a program-specific basis.

In response to the comments concerning our proposal to require a separate CMS Evaluation Form for each residency program for which the applicant hospital requests an increase in the number of FTE residents, we proposed such a requirement so that, as stated above and also in the proposed rule, we would be able to determine a hospital's "demonstrated likelihood" and to discern within which level priority category (first through sixth) the applicant hospital's application should be placed based on the residency specialty program for which the FTE cap increase is being requested. As we have stated, a hospital may apply for an increase in its FTE caps for more than one residency program at the hospital. It is possible that applications for the programs would fall within different level priority categories. For example, a hospital may apply for an increase in its cap(s) for one program that is the "only specialty training program in the State" (which would place the hospital's application in the fifth level priority category on the CMS Evaluation Form) and for another program that is not the only program in the State (which, assuming the hospital is located in a large urban area, would place the hospital on that Evaluation Form in the sixth level priority category). Therefore, we proposed that hospitals complete an Evaluation Form for each residency program for which it is requesting an increase in its FTE resident cap. For these reasons, we are finalizing our proposed policy. We believe it would be difficult for us to establish "demonstrated likelihood" and to determine which hospital requests should have priority over others to receive the section 422 cap without asking hospitals to submit a CMS

Evaluation Form for each program they are requesting as part of their application for the section 422 cap.

Finally, to respond to the comments concerning program-specific criteria on the CMS Evaluation Form, we proposed such criteria in an attempt to not only encourage certain public health and community goals, but also to correct certain anomalies relating to the FTE resident cap that may have been unintended consequences resulting from the BBA-mandated FTE caps. We believe our proposed program-specific criteria are important because we would, at least at the outset of awarding the section 422 cap increases, like to encourage certain behaviors in graduate medical education.

To demonstrate the point that the section 422 caps are hospital-specific and not program-specific, we give the following example to represent a scenario that we would view as an appropriate use of the section 422 caps:

Example: Hospital-specific section 422 caps

Hospital D, an urban hospital located in an other than large urban area that is training residents at its direct GME and IME 1996 FTE caps, applies to CMS for the section 422 caps because the hospital intends to expand its existing geriatrics residency program from 5 FTEs to 10 FTEs beginning July 1, 2005, and therefore checks off C2 on the CMS Evaluation Form and also demonstrates a likelihood of filling the slots of the program. CMS awards Hospital D 5 FTE residents for its direct GME and IME section 422 caps to be used by Hospital D beginning on or after July 1, 2005. In the middle of the 2008 program year, Hospital D realizes that it only had been able to increase its geriatrics residency program for two additional geriatrics residents. Hospital D would

accordingly prefer to use 3 FTEs for direct GME and IME out of its section 422 cap for another unrelated program, because it would like to expand the number of FTE residents that program. Thus, beginning July 1, 2009, Hospital D may count 2 FTE residents for geriatrics and 3 additional FTEs for another program in its section 422 caps.

Comment: One commenter asked whether "each residency program within a single hospital" must submit a separate CMS Evaluation Form.

Response: First, hospitals, not individual residency programs at hospitals, apply for the section 422 caps. As we have indicated earlier, the section 422 caps are not program-specific; rather, they are hospital-specific. Second, as discussed above and also in the proposed rule, we are requiring that each hospital submit as part of its application a separate CMS Evaluation Form for each residency program for which the applicant hospital intends to justify an increase in the number of FTE residents slots.

Comment: One commenter asked whether each hospital under a Medicare GME affiliation agreement should submit a CMS Evaluation Form for "the same specialty program."

Response: We are assuming the commenter is referring to a hospital that is applying for the section 422 cap increase and such a hospital will also participate in a Medicare GME affiliation agreement as of July 1, 2005, such that it is rotating residents in a particular program from the hospital to another hospital in the affiliation. We are clarifying in this final rule that--(1) hospitals that participate in a Medicare GME affiliation agreement under §413.79(f) on or after July 1, 2005, may apply for the increase to their caps under section 422; and (2) hospitals that receive section 422 cap

increases from CMS and participate in a Medicare GME affiliation agreement under §413.79(f) on or after July 1, 2005 may only affiliate for the purpose of adjusting their 1996 FTE caps (adjusted for new programs and any reductions under section 1886(h)(7)(A) of the Act) for direct GME and IME. The additional slots that a hospital receives under section 422 may not be aggregated and applied to the FTE resident caps of any other hospitals. Adjustments under section 422 are limited to no more than 25 FTEs for any hospital that applies. We believe that if we were to allow affiliations using the section 422 cap increases, hospitals could circumvent the 25 FTE limit on the section 422 cap increases. We also believe this prohibition on affiliations relating to the section 422 cap increases is needed to facilitate tracking for the different direct GME and IME payment rates associated with FTE residents that are counted as a result of the section 422 cap increases. It would be very difficult for both providers and fiscal intermediaries to identify these "422" FTE residents in an affiliation agreement with two or more hospitals (some affiliations have multiple hospitals participants). Therefore, we believe it is appropriate to prohibit hospitals that receive section 422 cap increases from including those FTE increases in the aggregate FTE cap in an affiliated group, effective July 1, 2005. However, hospitals that receive section 422 cap increases may affiliate with other hospitals using the remainder of their FTE resident caps, that is, the 1996 cap as adjusted for new programs and reductions under section 1998(h)(&)(A) of the Act. The following is an example of an affiliation between two hospitals (one of the affiliated hospitals has a section 422 cap for direct GME and IME):

Example: Affiliation agreement with section 422 caps

Hospital A has a 1996 FTE resident cap of 100 for both direct GME and IME and, effective July 1, 2005, a section 422 cap of 15 for both direct GME and IME. Hospital B has a 1996 FTE resident cap of 60 for both direct GME and IME and no section 422 cap. For the academic year ending June 30, 2006, the two hospitals enter into a Medicare GME affiliation agreement. Their combined 1996 direct GME and IME cap is 160 FTE residents (100 Hospital A + 60 Hospital B). The hospitals are prohibited from forming a Medicare GME affiliation agreement using the 15 FTE in Hospital A's section 422 cap. They may reallocate the 1996 FTE resident caps under the affiliation so that Hospital A's direct GME and IME 1996 cap is 90 and Hospital B's direct GME and IME 1996 cap is 70. Both Hospital A and Hospital B have a FYE of June 30. In addition to its 1996 cap of 90, Hospital A would have a section 422 cap(s) of 15 FTEs.

Hospital A: During FY 2006, Hospital A trains 100 FTE residents. Of the 100 FTE residents, Hospital A is able to count up to 90 FTEs in its 1996 cap as adjusted by the Medicare GME affiliation agreement described above and 10 residents as part of its section 422 cap.

- For direct GME, the 90 residents counted as part of the 1996 FTE cap are paid at the hospital's actual per resident amounts (primary care PRA and/or nonprimary care PRA) inflated to the current cost reporting period.

- For direct GME, the 10 FTE residents (100 total FTE – 90 FTE counted in the 1996 cap) that Hospital A counts above its 1996 FTE cap, as adjusted by the affiliation agreement, are counted as part of the section 422 cap. These 10 FTE residents are paid at

the locality-adjusted national average PRA under §413.77(d)(2)(ii), inflated to the current cost reporting period.

- In order to calculate the IME adjustment factor for the 90 FTE residents counted as part of the 1996 FTE cap, Hospital A uses 1.37 (per section 502(a) of Pub. L. 108-173) as the IME adjustment factor formula multiplier.

- In order to calculate the IME adjustment factor for the 10 FTE residents counted as part of the section 422 cap, Hospital A uses .66 (per section 422(b)(1)(C) of Public Law 108-173) as the IME adjustment formula multiplier.

- The remaining 5 FTE available under Hospital A's section 422 cap are unused during the FYE June 30, 2006.

Hospital B: During FY 2006, Hospital B trains 75 FTE residents. Of these 75 residents, only 70 residents are counted as a result of Hospital B's 1996 FTE cap as adjusted by the Medicare GME affiliation agreement.

- For direct GME, the 70 FTE residents counted as part of the 1996 FTE cap are paid at the hospital's actual per resident amounts (primary care PRA or nonprimary care PRA) inflated to the current cost reporting period.

- In order to calculate the IME adjustment factor for the 70 FTE residents counted as part of the 1996 FTE cap, Hospital B uses 1.37 (per section 502(a) of Pub. Law 108-173) as the IME adjustment factor formula multiplier.

Hospital B cannot receive Hospital A's unused section 422 cap slots through the affiliation agreement. Therefore, 5 FTE residents training at Hospital B cannot be counted for purposes of direct GME and IME payment.

Comment: One commenter asked for clarification on which hospitals are eligible to submit an application for the section 422 caps by March 1, 2005, rather than December 1, 2004.

Response: We stated at the proposed rule the following information for the timeframe for submission of the section 422 cap increase applications:

"We further propose that any hospital that wishes to receive an increase in its FTE resident cap(s) must submit a copy of its completed application … to the CMS Central Office and to the CMS Regional Office for the region in which the applicant hospital is located, and that the application must be received on or before December 1, 2004…We note that some hospitals' FTE counts will be subject to audit for purposes of section 1886(h)(7)(B) of the Act, and those audits may not be completed by December 1, 2004. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, we propose to allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for purposes of section 1886(h)(7)(A) of the Act, and that hospital also wishes to apply for an increase in its FTE resident cap(s) available through section 1886(h)(7)(B) of the Act, we propose that such a hospital must submit a completed application to CMS and that the application must be received on or before March 1, 2005." We hope this information is helpful and are finalizing the December 1, 2004 and March 1, 2005 deadlines applications for the different hospitals in this final rule.

i. CMS Evaluation of Applications for Increases in FTE Resident Caps

As noted in section IV.O.2.h. of this preamble, in the May 18, 2004 proposed rule, we proposed to require hospitals to submit, with their applications for increases in their FTE resident caps, a completed copy of the CMS Evaluation Form. As we have stated, we proposed to make the process of evaluating the applications as objective as possible. Therefore, we proposed to use a CMS Evaluation Form that the hospital must complete and submit as part of its application. The CMS Evaluation Form will ask the hospital to check off which of the "demonstrated likelihood" criteria (described above in section IV.O.2.g. of this preamble) the hospital meets. We also proposed to require the hospital to provide the documentation that supports the "demonstrated likelihood" criteria it has checked off on the Evaluation Form.

Assuming that hospitals interested in applying for the increase in their FTE caps meet the eligibility criterion of "demonstrated likelihood," we proposed that applicant hospitals indicate on the CMS Evaluation Form the category(ies) for which it believes it will qualify. We will use this indication to prioritize the applications. This prioritization is derived from section 1886(h)(7)(B) of the Act, as added by section 422 of Pub. L. 108-173. That section established the following priority order to determine the hospitals that will receive increases in their FTE caps:

- First, to hospitals that are "located in rural areas, as defined in section 1886(d)(2)(D)(ii) of the Act" (section 1886(h)(7)(B)(iii)(I) of the Act).

Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing implementing regulations at

§413.62(f)(ii), an "urban area" means (1) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA); or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing §413.62(f)(iii), a "rural area" means any area outside an urban area. However, we note that under section III. of this preamble, which discusses changes in wage areas for FY 2005, we proposed to no longer recognize NECMAs as a distinct category of wage areas. Thus, for purposes of the amendments made by section 422, we proposed that any hospital located in an area that is not in a MSA is a rural hospital, regardless of any reclassification under §412.102 or §412.103. We note that this definition of "rural" is consistent with our policy under section III. of this preamble concerning designation of wage index areas.

- Second, to hospitals that are located in urban areas that are not large urban areas, as defined for purposes of section 1886(d) of the Act (section 1886(h)(7)(B)(iii)(II) of the Act). Section 1886(d)(2)(D) of the Act defines "large urban area" as an "urban area which the Secretary determines . . . has a population of more than 1,000,000." Existing implementing regulations at §412.63(c)(6) state generally that the term "large urban area" means an MSA with a population of more than 1,000,000. Again, we note that we proposed changes to the definition of "urban area" to reflect the new geographic areas designated by the Office of Management and Budget under section III. of this preamble. Therefore, if the eligible hospital applying for an increase in its FTE resident cap is an urban hospital that is located in the proposed redefined MSA area with a

population of less than 1,000,000, CMS will give such a hospital second priority (after all rural hospitals in the first priority category under the statute) in deciding which hospitals should receive an increase in their FTE resident caps.

- Third, hospitals that currently operate, or will operate, a residency training program in a specialty for which there are not other residency training programs in the State (section 1886(h)(7)(B)(iii)(III) of the Act). We proposed to interpret "a specialty for which there are not other residency training programs in the State" to mean the only specialty in either allopathy or osteopathy in a particular State. For example, if in State X, Hospital A would like to use the additional FTE residents in order to establish a new osteopathic emergency medicine program (which would be the first osteopathic emergency medicine program in State X), and Hospital B has already established an allopathic emergency medicine program in State X, Hospital A's application for an increase in its FTE resident cap(s) would be put in the third priority category because Hospital A would be establishing a new osteopathic emergency medicine program, a specialty for which there are not other osteopathic emergency medicine programs in the State. We believe that a more "expansive" interpretation of "a specialty for which there are not other residency programs" allows more hospitals to fit into this third priority category. In addition, it is our understanding that allopathic and osteopathic programs are, at least, nominally different disciplines in medicine. As a result, we believe that this more "expansive" interpretation for "a specialty for which there are not other residency programs" is the more appropriate interpretation.

As we described above, we proposed that applicant hospitals indicate on the CMS Evaluation Form the category(ies) for which it believes it will qualify; we will use this indication to prioritize the applications. Each of the categories (described below) is derived from the priorities established by section 1886(h)(7)(B) of the Act, as added by section 422 of Pub. L. 108-173. We proposed to use the following categories to determine the order in which hospitals would be eligible to receive increases in their FTE resident caps:

First Level Priority Category: The hospital is a rural hospital and has the only specialty training program in the State.

Second Level Priority Category: The hospital is a rural hospital only.

Third Level Priority Category: The hospital is an urban hospital that is located in a "not large urban area" and has the only specialty program in the State.

Fourth Level Priority Category: The hospital is an urban hospital that is located in a "not large urban area."

Fifth Level Priority Category: The hospital has the only specialty training program in the State.

Sixth Level Priority Category: The hospital meets none of the statutory priority criteria.

We believe the first and third level categories are appropriate for our evaluation purposes (which is explained further below) because some hospitals that apply for the additional resident slots may fit into more than one of the three statutory priority categories listed in section 1886(h)(7)(B) of the Act. In addition, we proposed to give

consideration first to those hospitals that meet more than one of the statutory priority categories over those hospitals that meet only one of the statutory priorities (see second, fourth, and fifth level priority categories.) We also proposed a sixth level priority category to identify those section 1886(d) of the Act hospitals that apply for additional resident slots, but do not fit into any of the priority categories listed in section 1886(h)(7)(B) of the Act (that is, hospitals in large urban areas).

As specified by the statute, we proposed to put each hospital's application for an increase in its FTE resident cap (based on how the hospital describes itself on the CMS Evaluation Form) into one of the "level priority categories" for evaluation purposes, giving first and second priority to the rural hospitals, as defined above. In addition, we note that we proposed that hospital applicants provide residency specialty program information as part of the application for the increase to the cap(s), as well as a CMS Evaluation Form for each residency program for which the applicant hospital intends to use the increased FTE resident slots. Our intention in proposing these requirements was for CMS to be able to discern within which level priority category the applicant hospital's application should be placed based on the residency specialty program for which the FTE cap increase is being requested. In other words, it is possible that a hospital will apply for an increase in its FTE caps for more than one residency program at the hospital. It is possible that applications for the programs would fall within different level priority categories, for example, if a hospital in a large urban area is applying for an increase in its cap(s) for one program that is the "only specialty training program in the State" would place the hospital's application in the fifth level priority category on the CMS Evaluation

Form. For another program that is NOT the only program in the State, for a hospital in a large urban area, would place the hospital on that Evaluation Form in the sixth level priority category. Therefore, we proposed that hospitals complete an Evaluation Form for each residency program for which it is requesting an increase in its FTE resident cap.

Comment: Several commenters supported our proposals on the level priority categories, as stated in the proposed rule. One commenter stated that it was "extremely appreciative that CMS included a sixth category, for hospitals that do not meet any of the statutorily defined priority criteria (for example, hospitals located in large urban areas), within the priority ordering."

Response: We appreciate the commenters' support of the our proposals concerning the level priority categories.

Comment: We received several comments that addressed our interpretation of the third statutory priority at section 1886(h)(7)(B)(iii)(III) of the Act, which granted priority for a "residency program for which there are not other residency training programs in the State." Several commenters were very supportive of our proposed interpretation of this language to mean "the only specialty in either allopathy or osteopathy in a particular State." One commenter stated: "[w]e strongly support this approach, and we believe it appropriately reflects the fact that osteopathic and allopathic disciplines offer residents- and patients-different approaches to health care."

Another commenter, while supportive of our proposed implementation of section 1886(h)(7)(B)(iii)(III) of the Act, requested that we include interpretation that addresses a family medicine specialty which trains residents to care for "special populations—the

underserved who require care to be delivered by physicians who have had special language and cultural training because the population served required it."

Finally, another commenter asked us to clarify whether a hospital would be "the only program in the state" under section 1886(h)(7)(B)(iii)(III) of the Act, if the only other residency program in the state for a particular specialty is at a Federal or military hospital.

Response: We are pleased that the commenters are supportive of our proposed interpretation of "the only specialty in either allopathy or osteopathy in a particular State." We are finalizing this interpretation with this final rule.

In response to the second comment, we believe we have limited discretion in interpreting the statutory priorities to accommodate the situation of a family practice program in which residents treat underserved populations, unless a family practice program in a particular state is the only family medicine program in that state. However, we hope we *have* accommodated hospitals that strive to serve "special populations" by proposing many of the Evaluation Criteria on the CMS Evaluation Form (see, for example, Evaluation Criteria Three or Seven).

Finally, in response to the third comment, we understand that residency programs at Veteran's Affairs, Department of Defense, or other Federal hospitals *are* accredited program by either the ACGME or the AOA. Just because many of these military and Federal hospitals do not receive Medicare direct GME and IME payments for the training of interns and residents, does not mean that the residency programs at these hospitals do not exist for purposes of section 1886(h)(7)(B)(iii)(III) of the Act. Therefore, we are

clarifying here that if the residency program is accredited, even if that program is training residents at a Federal facility or military hospital, that program specialty exists for purposes of interpreting section 1886(h)(7)(B)(iii)(III) of the Act.

Comment: We received several comments objecting to the priority for the increase to the cap under section 422 to rural hospitals. One commenter believed that the proposed first and second level priority categories to rural hospitals "will undermine the expansion plans of many urban teaching hospitals, especially those that share the same corporate structure and are part of a multi-hospital system." The commenter requested that CMS remove the rural hospitals as the first and second level priorities for the increase to the caps under section 422.

Response: We believe we have limited statutory discretion in determining which hospitals should receive the increase to their caps under section 422. Our proposed level priority categories are derived from section 1886(h)(7)(B) of the Act, as added by section 422 of Public Law 108-173. That section established a priority order to determine the hospitals that will receive increases in their FTE caps. Section 1886(h)(7)(B)(iii)(I) of the Act of the Act gives first priority to hospitals that are "located in rural areas". We understand there may be situations where urban hospitals, due to circumstance, stand to lose FTE slots because of section 1886(h)(7)(A) of the Act, and the increase to the caps under section 1886(h)(7)(B) of the Act gives first priority to rural hospitals. However, the statute that mandated the priorities determines this situation.

Comment: We received one comment requesting that CMS give priority under the section 422 cap increase to hospitals in small urban areas that are Level 1 Trauma Centers.

Response: While we do not believe we have discretion in interpreting the priority categories, we believe that hospitals that are Level 1 Trauma Centers provide good emergency services to the public. Along these lines, we have agreed to add a new Evaluation Criterion 14 with this final rule (see below) that addresses residency training for new or expanding residency programs in emergency medicine.

Comment: We received one comment on the priority categories generally that requested that CMS refine its methodology so that hospitals that "already exceed their FTE caps are given first priority within their Priority category."

Response: As we have stated, the Congress has set the priorities as to which hospitals should receive the increase to their FTE caps first, without stating specifically that the hospitals applying for the cap increase must be at or above its FTE caps to qualify for the increase. However, as we believe, like most commenters, that most hospitals that apply for the section 422 caps will be above their 1996 FTE caps, we have agreed to add new Evaluation Criterion 12 to address the situation of hospitals exceeding their FTE caps (see discussion of Evaluation Criteria below).

CMS Evaluation of Application for Increases in FTE Resident Caps

We note that section 1886(h)(7)(B)(iii) of the Act states that "increases of residency limits within the same priority category . . . shall be determined by the Secretary." Therefore, we proposed to use the following criteria for evaluating the

applications for increases in hospitals' FTE resident caps within each of the six level priority categories described above:

Evaluation Criterion One. The hospital that is requesting the increase in its FTE resident cap(s) has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report. We have selected 60 percent utilization because it will identify hospitals where Medicare beneficiaries will benefit the most from the presence of a residency program, and it is consistent with the utilization percentage required for Medicare-dependent, small rural hospitals (MDHs) as specified in §412.108. In addition, it identifies a type of hospital that warrants atypical treatment by the Medicare program because it is so reliant on Medicare funding.

Evaluation Criterion Two. The hospital will use the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program. We believe that, of all the medical specialties, geriatrics is the one specialty that is devoted primarily to the care of Medicare beneficiaries. In addition, we note that encouraging residency training in geriatrics is consistent with Congressional intent as expressed, among other places, in section 712 of Pub. L. 108-173.

Evaluation Criterion Three. The hospital does not qualify for an adjustment to its FTE caps under existing §413.86(g)(12) (proposed to be redesignated as §413.79(k) in the proposed rule) for a rural track residency program, but is applying for an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act because it rotates (or in the case of a new program, will rotate) residents for at least 25 percent of the duration of the

residency program to any combination of the following: a rural area, as defined in section 1886(d)(2)(D)(ii) of the Act and §412.62(f)(1)(iii) of the regulations; a rural health clinic (RHC), as defined in section 1861(aa)(1) of the Act and §491.2 of the regulations; or a Federally Qualified Health Center (FQHC), as defined in section 1861(aa)(3) of the Act and §405.2401(b) of the regulations. We believe that the Congress intended that the Secretary use section 422 to encourage resident training in rural areas, and we believe this criterion furthers this intention. We proposed to include residency training in FQHCs in this criterion because we understand that some FQHCs are located in rural areas. In addition, we indicated our encouragement of residency training at FQHCs because we believe that, similar to rural providers and RHCs, FQHCs provide services for medically underserved areas or populations, or both.

Evaluation Criterion Four. In portions of cost reporting periods prior to July 1, 2005, the hospital qualified for a temporary adjustment to its FTE cap under existing §413.86(g)(9) (proposed to be redesignated as §413.79(h) in the proposed rule) because it was training displaced residents from either a closed program or a closed hospital, and, even after the temporary adjustment, the hospital continues to train residents in the specialty(ies) of the displaced residents and is training residents in excess of the hospital's direct GME FTE cap or IME FTE cap, or both, for that reason. We believe this criterion is appropriate because it will help to sustain the level of residency training in the community.

Evaluation Criterion Five. The hospital is above its FTE caps because it was awaiting accreditation of a new program from the ACGME or the AOA during the base

period for its FTE cap(s), but was not eligible to receive a new program adjustment as stated under existing §413.86(g)(6)(ii) (proposed to be redesignated as §413.79(e)(2) in the proposed rule). Under existing §413.86(g)(6)(ii) and §413 .86(g)(13) (proposed to be redesignated as §413.79(l) in the proposed rule), a hospital that had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996 could receive an adjustment to its unweighted FTE cap for a new medical residency training program that either received its initial accreditation or began training residents on or after January 1, 1995 and on or before August 5, 1997. If a hospital failed to meet those deadlines, it was not eligible to have its cap(s) adjusted to include residents in a new program. Under the proposed criterion, a hospital would apply for additional FTE residents if the hospital had submitted its application for a new program to the accrediting body before August 5, 1997, and received its accreditation after August 5, 1997 but before August 5, 1998. This would allow some hospitals to receive increases in their FTE resident caps in cases in which, in good faith, the hospital had submitted an application for accreditation for a new program prior to the date of enactment of FTE resident caps under the BBA, but because of the timing of the implementation of the FTE resident cap(s), had not yet received direct GME and IME payment for residents in the newly accredited program during the base period for the hospital's FTE resident cap(s).

Evaluation Criterion Six. The hospital is training residents in excess of its FTE resident caps because, despite qualifying for an FTE cap adjustment for a new program under §413.86(g)(6)(i) or (g)(6)(ii) (proposed to be redesignated as §413.79(e)(1) and

(e)(2) in the proposed rule), it was unable to "grow" its program to the full complement of residents for which the program was accredited before the hospital's FTE resident cap was permanently set beginning with the fourth program year of the new program. Similar to evaluation criterion five above, this criterion would allow some hospitals that had, in good faith, started up a new residency program as required in the regulations but could not completely fill the new program within the allowed regulatory period, to receive increases in their FTE resident caps. For instance, this could have occurred because the program was a program of long duration (such as a 5-year general surgery program), and the hospital did not have the opportunity to "grow" the program to its full complement of residents because the regulations at §§413.86(g)(6)(i) or (g)(6)(ii) allow a program to grow for only 3 years before the hospital's FTE resident cap is permanently adjusted for the new program.

Evaluation Criterion Seven. The hospital is located in any one (or a combination) of the following: a geographic HPSA, as defined in 42 CFR 5.2; a population HPSA, (also defined at 42 CFR 5.2); or a Medicare physician scarcity county, as defined under section 413 of Pub. L. 108-173. We proposed to use this 3-part criterion in order to capture, as objectively as possible, medically underserved areas or patient populations (many of which are Medicare beneficiaries), or both. We understand that if a particular community has been designated a HPSA (either a geographic or population HPSA), the designation information is available to hospitals from the Health Resources and Services Administration (HRSA) HPSA database at the website: **http://belize.hrsa.gov/newhpsa/newhpsa.cfm**. In addition, hospitals will be able to

determine whether they are located in a Medicare physician scarcity county (consistent with section 413 of Pub. L. 108-173) on the CMS Internet website at **www.cms.hhs.gov** or upon publication of the annual final rule setting forth the Medicare physician fee schedule (which is generally published by November 1 of each year). We note that if Medicare does not publish the final rule setting forth the Medicare physician fee schedule in time for the application deadline for increases in FTE resident caps (December 1, 2004, or March 1, 2005, depending on the hospital), we proposed that we will not use the Medicare physician scarcity county designations (as defined under section 413 of Pub. L. 108-173) for purposes of this criterion.

Evaluation Criterion Eight. The hospital is in a rural area (as defined under section 1886(d)(2)(D)(ii) of the Act) and is a training site for a rural track residency program (as specified under §413.86(g)(12) (proposed to be redesignated as §413.79(k) in the proposed rule)), but is unable to count all of the FTE residents training at the rural hospital in the rural track because the rural hospital's FTE cap is lower than the hospital's unweighted count of allopathic or osteopathic FTE residents beginning with portions of cost reporting periods on or after July 1, 2005.

Evaluation Criterion Nine. The hospital is affiliated with a historically Black medical college. According to the language in the Conference Report for Pub. L. 108-173 (pages 204-205), the Conference agreement on section 422 generally restated the three statutory priority categories described above (rural, "small" urban, and only specialty program in the State) in terms of giving guidance to the Secretary for deciding which hospitals should receive the redistributed FTE resident slots. However,

there was one additional cited criterion that the Conference indicated the Secretary should use in evaluating the hospital applications. Specifically, the Conference agreement states that the Secretary should consider whether the hospital is a "historically large medical college" (emphasis added). Upon consideration of this particular terminology, which, on its face, seems to contradict the three statutory priority categories (that is, rural, "small" urban, and only specialty program in the State), we proposed to view the reference to "historically large medical colleges" as a scrivener's error, and to read this language to refer to "historically Black medical colleges." This proposed interpretation accomplishes two goals: first, we believe this interpretation serves the greater policy goal of encouraging residency training for the benefit of medically underserved populations. Second, we believe that this interpretation reflects the Conferees' intent in the language in the Conference Report. In addition, we proposed to identify "historically Black medical colleges" as Howard University College of Medicine, Morehouse School of Medicine, Meharry Medical College, and Charles R. Drew University of Medicine and Science. These four medical schools are identified as "historically Black medical colleges" by the American Medical Association (see **http://www.ama-assn.org/ama/pub/category/7952.html**). We proposed that the hospital will meet this criterion if it intends to use an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act to count residents in residency programs sponsored by any of the historically Black medical college listed above.

Evaluation Criterion Ten. The hospital is training residents in residency program(s) sponsored by a medical school(s) that is designated as a Center of Excellence

for Underserved Minorities (COE) under section 736 of the Public Health Service Act in FY 2003. We understand that the COE program was established to be a catalyst for institutionalizing a commitment to underserved students and faculty, and to serve as a national resource and educational center for diversity and minority health issues. Therefore, we believe that it is appropriate to encourage hospitals to train residents in residency programs sponsored by medical schools that are designated as COEs. A hospital can verify whether it is training residents in programs sponsored by a medical school that is a COE. Medical schools that are COEs in FY 2003 are listed at the following website: **http://bhpr.hrsa.gov/diversity/coe/grantees2003.htm**. We note that, in FY 2003, there were 28 medical schools that were designated to be COEs.

In the May 18, 2004 proposed rule, we proposed to use the above set of criteria to evaluate the applications by hospitals for increases in their FTE resident caps that fall within each of the six level priority categories. We proposed to place each application in the appropriate priority level category based on a review of the information the hospitals check off on the proposed CMS Evaluation Form for each allopathic and osteopathic specialty program requested by the applicant hospital, and the corresponding requested FTE cap increase (see the proposed form below). We proposed to place all of these evaluation criteria on the Evaluation Form and to ask the hospital to check off which criteria on the form apply for each specialty program for which an FTE cap increase is requested. Based on the assertions checked off on the form, we would score each CMS Evaluation Form (one point per criterion checked off). The higher scoring CMS Evaluation Form(s) for each applicant hospital within each level priority category would

be awarded the FTE resident cap increases first. As we described above, we proposed to award the cap increases in the order of the six specified level priority categories because, as a general rule, we believe hospitals that meet more than one of the statutory priorities should be awarded the increases in their FTE resident caps first before other hospitals. We also believe that hospitals that meet a higher statutory priority category should receive first consideration by us over hospitals that meet lower statutory priorities. That is the reason, for instance, we proposed the first level (rural hospital + only specialty program in the State) and second level (rural only) priority categories to give all rural hospitals first consideration by us before any small urban hospital, as required by the statute.

Thus, first level priority category hospitals that score highest on the evaluation criteria on the CMS Evaluation Form for a particular specialty program would receive the increases in their FTE resident caps first. For example, if Hospital D is a rural hospital and is establishing the first osteopathic internal medicine residency program in State Y, thereby falling within the first level priority category, and Hospital D checks off on the CMS Evaluation Form that it has a Medicare utilization of 60 percent, is located in a geographic HPSA, and is affiliated with a historically Black medical college, Hospital D would receive a score of 3 points on the completed CMS Evaluation Form. We proposed that we would first award FTE cap increases to hospitals whose CMS Evaluation Forms for a particular program receive 10 points based on the number of evaluation criteria checked off by the hospital for the program (if there are any) and then to those with successively fewer points within the level priority category. Hospital D would receive

the increase in its FTE resident cap(s) requested on its application after all the hospitals in the first level priority category whose applications receive 10 through 4 points are awarded their requests first.

We proposed that we would award the increases in FTE resident caps to all those hospitals that are in the first level priority category (rural hospitals + only specialty program in the State) before evaluating those hospitals in the second level priority category (rural hospital), and would award the FTE resident slots to all those hospitals in the second level priority category before evaluating those hospitals in the third level priority category ("small" urban hospital + only specialty in the State), and so on. Once we reach an aggregate number of FTE resident cap increases from the aggregate estimated pool of FTE resident positions under section 1886(h)(7)(A) of the Act, but are unable, based on the number of remaining slots, to meet all of the requests at the next level priority category at the next score level, we proposed to prorate any remaining estimated FTE resident slots among all the applicant hospitals within that level priority category and with the same score on the hospital's application.

For example, assume all applicant hospitals in the first through fourth level priority categories receive the requested increases in their FTE resident caps by us, and we evaluate hospital applications next and accompanying CMS Evaluation Forms in the fifth level priority category (only specialty program in the State). At the point that we have awarded cap increases for all the fifth level priority category hospitals that scored 5 or above on their CMS Evaluation Forms for each residency program, we find that there is only a sufficient number of resident slots remaining in the estimated pool to grant half

of the requests for slots from hospitals that scored 4 points. We proposed that we would prorate all of the remaining FTEs among the 4-point CMS Evaluation Forms and accompanying applications in the fifth level priority category. Thus, if we could have awarded a total of 200 FTE slots for direct GME and 185 FTE slots for IME to only the first 50 percent of the 4-point CMS Evaluation Forms in the fifth level priority category at the point that the estimated pool of FTE slots is spent, we proposed to prorate all of the 200 FTE slots for direct GME and 185 FTE slots for IME among all of the 4-point CMS Evaluation Forms and accompanying applications in that fifth priority category, no matter what level of FTE resident cap increase was requested on the individual hospital's application.

We recognize the complexity of the proposed evaluation process for the award of increases in hospital's FTE resident caps under section 1886(h)(7)(B) of the Act. Therefore, we have included the following examples depicting the proposed procedures:

Example 1

Hospital M in State Z is an urban hospital located in an MSA that has a population of less than 1 million. Hospital M can demonstrate the likelihood that it will fill the requested five FTEs resident slots for direct GME and IME for a geriatric program because it is currently training a number of FTE residents that exceeds both of its FTE caps, and has attached to its application for an increase in its FTE resident caps a copy of Hospital M's past three Medicare cost reports (as filed or audited, whichever is most recent and available), which documents on Worksheet E, Part A and Worksheet E3, Part IV that, according to the resident counts and the FTE resident caps, Hospital M is training

residents in excess of its caps. Hospital M has taken on geriatric residents from a teaching hospital in the community that closed, and is also located in a Medicare physician scarcity county.

We would evaluate Hospital M's application accordingly. It will be determined a fourth level priority category ("small" urban hospital); and will receive a score of 4 (expanding geriatrics program, Medicare physician scarcity area, residents from a closed hospital, training residents in excess of its 1996 FTE caps).

Example 2

Hospital K is a large academic medical center located in an MSA with a population of greater than 1,000,000 and is in a population HPSA. Hospital K regularly trains residents in programs sponsored by Meharry Medical College, and wishes to add more residents from Meharry, and therefore, has requested accreditation from the ACGME to expand the number of Meharry residents training in both allopathic surgery and osteopathic pediatrics programs. Hospital K is above both its direct GME and IME FTE caps.

Hospital K's CMS Evaluation Forms for allopathic surgery and osteopathic pediatrics would be submitted separately by the hospital and we would evaluate it (separately) accordingly. Both requests would put the hospital in the sixth level priority category (large urban hospital); it can demonstrate the likelihood of filling the slots (because Hospital K can document both that the hospital is above its caps and that it has requested ACGME accreditation to expand the programs); and will receive a score of 3

(population HPSA, historically Black medical college, training residents in excess of its FTE caps).

Example 3

Hospital E is a rural hospital located in a Medicare physician scarcity area and a geographic HPSA. It is a rural training site for an already established rural track residency program that has only been a training site since 2002. Therefore, Hospital E has an FTE resident cap of zero FTEs for direct GME and IME.

Hospital E's CMS Evaluation Form for the rural track family practice program and accompanying application would be evaluated by us accordingly. Second level priority category (rural hospital); it can demonstrate the likelihood of filling slots (because Hospital E can document that it is both over its cap of zero FTEs, and that it is a training site for an accredited rural track residency program; and will receive a score of 3 (a training site for a rural track, and a Medicare physician scarcity area, and a geographic HPSA, and training residents in excess of its FTE caps).

Example 4

Hospital W is a rural hospital that has FTE caps of 15 FTEs for both direct GME and IME. Hospital W requests a total FTE cap adjustment of 25 FTEs for both direct GME and IME; 5 FTEs are to expand an existing geriatric fellowship; and 20 FTEs are to establish the first osteopathic emergency medicine program in State K, in which Hospital W is located. Hospital W can document that it is at its FTE caps with existing residency programs. We would make the following assessment for Hospital W's Evaluation Form for the geriatric fellowship: Hospital W falls into the second level priority category for

being a rural hospital; it can demonstrate the likelihood that it will fill the 5 FTE slots of the geriatric program by documenting that it has requested additional slots in the accreditation of the geriatrics program. Hospital W would receive a score of 1on its CMS Evaluation Form for the geriatrics program. We would make the following assessment for Hospital W's CMS Evaluation Form for the new osteopathic emergency medicine program: Hospital W would meet the first level priority category for this Evaluation Form because, not only is it a rural hospital, but it is also requesting 20 FTEs for the only osteopathic emergency medicine program in the State; it can demonstrate the likelihood that it will fill the 20 osteopathic emergency medicine FTEs by documenting the accreditation request and also that it is over its FTE caps. Hospital W would receive a score of zero, because it did not meet any of the evaluation criteria on the CMS Evaluation Form. Although this request receives a score of zero, it will be granted its request as level one priority request before any other level priority category.

Comment: We received many comments in general support for our proposed evaluation criteria on the CMS Evaluation Form. One commenter stated: "[w]e applaud CMS in attempting to meet not just the letter of the law, but the spirit, in crafting its priority list to include priorities such as rural and underserved areas, minority institutions, etc." Another commenter stated that "[a]lthough the evaluation process as a whole is lengthy and confusing, we note that several of the individual criteria respond to longstanding problems with the way resident caps were determined under the BBA...We applaud CMS' decision to address these problems now through the resident redistribution

process." The commenter listed the proposed Evaluation Criteria Four, Five, and Six as serving this purpose.

Response: We appreciate the commenters' support of our proposals in this section.

Comment: Many commenters supported our proposed Evaluation Criterion Two, which states that the "hospital needs the additional slots to establish a new geriatrics residency program, or adding residents to an existing geriatrics program." Many of these commenters were pleased with CMS' acknowledgment in the proposed rule that "geriatrics is the one specialty that is devoted primarily to the care of Medicare beneficiaries" and strongly urged CMS to include this geriatrics language for Evaluation Criterion Two in this final rule. One commenter, in support of CMS finalizing the proposed Evaluation Criterion Two concerning geriatric programs, stated: "[a]s evidenced in a recent study published in Health Affairs (Apr 7, 2004), in states with higher concentrations of [general practitioners], Medicare spends less money per beneficiary and gets better quality. And the opposite is true for states with higher specialist concentrations."

Response: We appreciate the commenters' support of our proposal to include a point in the Evaluation Criteria for residency training in geriatrics residency programs. We are accordingly finalizing this proposed criterion in this final rule.

Comment: Two commenters requested that CMS add a new criterion to the evaluation criteria to evaluate the hospital applications for the increase in hospitals' FTE caps that would give hospitals a point in their applications if the hospital will use the

additional slots to establish a new family practice program, or add residents to an existing family practice program.

Response: We agree to add a new evaluation criterion on the CMS Evaluation Form in this final rule that addresses primary care residency training, because we believe there is a statutory basis in the Medicare program for encouraging primary care residency training. The statute at section 1886(h) of the Act cites primary care programs for special treatment. For example, with both primary care and non-primary care programs, the statute has permanently assigned a higher direct GME PRA for the hospital's primary care residency programs. As specified at section 1886(h)(5)(H) of the Act, "primary care resident" means "a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice." We are incorporating this definition at §413.75(b). Therefore, in this final rule, we are including a new Evaluation Criterion 11 to read as follows:

"C11: Evaluation Criterion 11. The hospital needs the additional slots to establish a new primary care residency program, or to expand an existing primary care residency program, as primary care is defined under §413.75(b)."

Comment: We received several comments asking CMS "to favor rural and other underserved training sites" in determining priority for the increase under section 422.

Response: By proposing such criteria as Evaluation Criteria Three or Seven, we believe we have addressed awarding hospitals that train residents in rural and

underserved areas. We are finalizing the proposed criteria on these issues, as well as adding new Evaluation Criteria that may also address these issues.

Comment: We received several comments concerning our proposed Evaluation Criterion Four, which states--

"In portions of cost reporting periods prior to July 1, 2005, the hospital qualified for a temporary adjustment to its FTE cap under existing §413.86(g)(9) (proposed to be redesignated as §413.79(h) in the proposed rule) because it was training displaced residents from either a closed program or a closed hospital, and, even after the temporary adjustment, the hospital continues to train residents in the specialty(ies) of the displaced residents and is training residents in excess of the hospital's direct GME FTE cap or IME FTE cap, or both, for that reason."

One commenter noted that hospital closure "is not the only chaotic factor with which existing teaching hospitals in a given area must cope…changes in a community's demography and needs, the hospital's facilities and resources, and the resident training programs of other hospitals…" are other factors that hospitals consider when deciding use of a resident slots. Therefore, the commenter requested that CMS consider a "key priority" for the redistribution of unused positions under section 422 should be "to keep the slots within the original MSA, or for resident slots lost by facilities not in an MSA, within the original state." Similarly, other commenters requested that CMS modify the proposed Evaluation Criterion 4 to address hospitals that are training residents from one or more hospitals in its community "who have downsized their residency program(s) but

did not close these programs." One commenter believed that this "downsizing" could occur because the Residency Review Committee (RRC) required the downsizing.

Another commenter requested that CMS consider modifying this evaluation criterion to account for a hospital that that "qualified for a temporary adjustment because it was training displaced residents from either a closed program or a closed hospital *regardless* of whether the [hospital] continued to train residents in that specialty." The commenter believed that CMS should "award" hospitals that served a "distinct public good," regardless of whether they continued to train residents in the same specialty.

One commenter recommended that CMS change the criterion to a requirement of documentation of acceptance of the resident(s) from the closed hospital/closed program plus proof of "closure notice."

Finally, another commenter encouraged CMS to "keep closed hospital resident slots in the community by distributing those slots to the facility that completed the training of those residents, with permanent count increases."

Response: We recognize that there are many considerations that hospitals must take into account when determining the need for more resident slots, including the need for more training within a community, hospital (or program). However, in including Evaluation Criterion Four, we did not intent to attempt to maintain resident levels on a state or MSA basis. Rather, we were only addressing concerns that have been brought to our attention by hospitals that have, in the past, provided for training residents from either closed hospitals or closed programs. We also do not agree with the commenter that we

should address the need of hospitals that take on the training of residents from hospitals where programs are "downsized."

To address the second commenter's suggestion on modifying the criterion to award hospitals that received the temporary adjustment to the cap for training residents from programs or hospitals that closed, regardless of whether the hospitals continue to train residents in the same specialty, we proposed Evaluation Criterion Four because we believed it would address an issue left unresolved by the temporary adjustment for closed hospitals or programs. We understand from speaking to many hospitals that took on the training of displaced residents, that they continued to have cap problems long after they had received the temporary cap adjustment under §413.79(h), since these hospitals continued to train other residents in those slots even after the original displaced residents completed their training. Because we understand that the specialty program at the hospital that allowed the displaced residents to complete their training continues to fulfill a need in the community of the hospital for training in that program, we believe our Evaluation Criterion Four should be finalized as proposed, thereby rewarding those hospitals that serve this community in this fashion.

To address the comment requesting that, instead of the hospital documenting that the hospital had qualified for a temporary adjustment to its cap and was still training residents in the same specialty, that CMS should look to whether the hospital documented "acceptance of the resident" and "proof of closure," as we stated above, by proposing Evaluation Criterion Four, we attempted to address the specific situation of a hospital continuing to have cap problems as a result of training more residents in that program

long after it had received the temporary cap adjustment under §413.79(h). We understand that there are multiple situations of hospitals training residents from a closed hospital/program; however, we believe the documentation requirements in the proposed criterion more closely reflects the situation we intended to address. Therefore, we are not adopting the commenters changes in this final rule.

Finally, to address the commenter's concern with our awarding hospitals permanent cap adjustments that take on residents from closed hospitals, we hoped to do so by proposing the Evaluation Criterion Four. While there is no guarantee that hospitals that meet Evaluation Criterion Four necessarily receive the section 422 caps (that is, the permanent cap adjustments sought by the commenter), we attempted to acknowledge the important role and "public good" such hospitals serve by finalizing Evaluation Criterion Four.

Comment: Many commenters believed that, generally, only hospitals that are counting FTE residents that exceed their 1996 FTE caps for direction GME and/or IME would be interested in applying for the section 422 caps. One commenter stated: "[a] primary purpose (if not the primary purpose) of section 422 [in Pub. L. 108-173] is to provide 'cap relief' to hospitals that have resident counts that exceed their caps." Therefore, the commenters believed that CMS should reflect the situation of a hospital exceeding its 1996 FTE cap in the evaluation criteria on the CMS Evaluation Form.

In addition, two commenters believed that CMS should assign special weighting factors or extra points (rather than just one point per evaluation criterion as stated in the proposed rule) to such a criterion on the final CMS Evaluation Form. Similarly, another

commenter believed that CMS should adjust the Evaluation Criteria to include 0-2 points based on the percentage by which the applicant hospital's projected FTE count is in excess of 1996 FTE caps.

Response: Although we believe we may have already addressed the concern of hospitals exceeding their 1996 FTE caps in some of the evaluation criteria on the CMS Evaluation Form, we agree with the commenters that a primary purpose of the Congress of writing section 422 is to address situations of "cap relief" for hospitals that have exceeded their caps. Therefore, we are adding another criterion to the final evaluation criteria on the CMS Evaluation Form that states--

"C12: Evaluation Criterion 12. The hospital is above its direct GME and/or IME FTE cap on the count of residents, as stated in the Medicare cost report on the worksheets E, part A or the worksheets E3, part IV, in the hospital's most recently as submitted Medicare Cost Report."

Because we are also finalizing the other Evaluation Criteria on the proposed CMS Evaluation Form that address hospitals that exceeded their caps, we are not awarding extra weighting factors or extra point(s) to the new "exceed FTE cap" Evaluation Criterion, as the commenters suggested. We already believe that we are awarding two points for those hospitals that meet any of the proposed Evaluation Criteria (that are finalized with this final rule) plus the new "exceed FTE cap" criterion. For the same reason, we will not be "prorating" points based on how much an applicant hospital is projecting it will exceed its 1996 FTE caps. Therefore, we will only be awarding one

point if a hospital meets the "exceed FTE cap" evaluation criterion on the CMS Evaluation Form.

Comment: We received several comments asking CMS to include recognition in the evaluation criteria on the CMS Evaluation Form of emergency medicine residency programs. Two commenters stated that "[e]mergency physicians are required to see a large number of patients to gain experience and clinical expertise across a large range of injuries and illnesses they will need to diagnose and treat." Along a similar vein, these commenters believe that CMS should recognize programs that include "bio-terrorism and disaster preparedness training and coordination with State EMS organizations and the Department of Homeland Security."

Response: Because the Congress has specifically addressed the importance of emergency physicians and bio-terrorism preparedness, (see, for example, the Conference Report accompanying H.R. 2673, page 803, Report 108-401, we agree to add a point in the Evaluation Criterion on the CMS Evaluation Form in this final rule to address emergency medicine programs that include bio-terrorism training as part of their programs. New Evaluation Criterion 14 states--

"C14: Evaluation Criterion 14. The hospital is above its cap and needs the additional slots to establish a new emergency medicine residency program or expand an existing emergency medicine residency program. The emergency medicine residency program includes training in bio-terrorism preparedness."

Comment: We received several comments on the proposed Evaluation Criterion One that gives a point to a hospital that "is requesting the increase in its FTE resident

cap(s) [and] has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report."

Two commenters stated that, because of the time lag associated with settling Medicare cost reports, CMS should accept submitted Medicare cost reports for the proposed Medicare utilization Evaluation Criterion. The commenters also believed that "CMS … should consider modifying this criterion to include Medicare share based only on Medicare inpatients as a share of Medicare and privately insured patients. Many teaching hospitals treat a significant number of Medicaid and uninsured patients and they should not be disadvantaged."

We received several comments suggesting that instead of relying on the Medicare inpatient percentage, CMS should consider hospitals that are eligible for Medicare Disproportionate Share Hospitals (DSH) payments. Another commenter stated that CMS should consider any hospital that has a Medicare DSH percentage greater than 25%, "since that is an indicator that the hospital is serving a disproportionate share of low income patients."

Another commenter requested that we modify the Evaluation Criterion so that a hospital would qualify if it had a Medicare inpatient utilization of 50 percent or greater. Finally, another commenter suggested that we modify this Evaluation Criterion so that a hospital would qualify if its inpatient utilization for Medicare, Medicaid and uninsured patients is over 60 percent.

Response: As we stated in the proposed rule at 69 FR 28302, we proposed Evaluation Criterion One because we believe 60 percent would "identify hospitals where Medicare beneficiaries will benefit the most from the presence of a residency program, and it is consistent with the utilization percentage required for Medicare-dependent, small rural hospitals (MDHs) as specified in §412.108. In addition, it identifies a type of hospital that warrants atypical treatment by the Medicare program because it is so reliant on Medicare funding." We modeled the proposed Evaluation Criterion One off of the Medicare policy concerning MDHs, which at §412.108, specifies, among other things, that the hospital must capture the Medicare utilization "on at least two of the hospital's last three most recent audited cost reporting periods for which there is the Secretary has a settled cost report." We continue to believe that the 60 percent threshold is appropriate for purposes of establishing priorities under section 422, and based on the hospital's post recently settled cost reports. Therefore, we are not adopting the commenters' proposal to accept submitted Medicare cost reports or to lower the threshold of Medicare inpatient utilization to 50 percent or greater to meet this Evaluation Criterion.

In addition, we are not adopting the commenters' proposal to include inpatient Medicare utilization based as a share of Medicare and privately insured patients, or as a share of Medicare, Medicaid and uninsured patients, for purposes of the Evaluation Criterion One. It has been a longstanding policy for Medicare Part A payments, including in Medicare graduate medical education patients, that Medicare inpatient utilization is calculated based upon a hospital's Medicare inpatient days divided by total hospital inpatient days. The "total hospital inpatient days" has always included any

patients admitted in a hospital—that would include uninsured patients, privately insured patients and others. We do not believe it is appropriate to interpret "total hospital inpatient days" to include only Medicare patients and privately insured patients; doing so, would allow hospitals to have higher "Medicare inpatient utilization" for purposes of meeting this evaluation criterion than they would ordinarily for purposes of any other Medicare payments.

In response to the suggestions that we should look at hospital eligibility for Medicare DSH or look at whether the hospital has a Medicare DSH percentage of 25 percent instead of looking at the 60 percent of Medicare inpatient utilization for the applicant hospital, we do not believe these indicators show a commitment to Medicare populations. Rather, these indicators measure Medicaid and SSI beneficiaries treated at the hospital as a proxy for uncompensated care. Accordingly, we continue to believe that Medicare utilization is the way for hospitals to demonstrate their commitment to Medicare populations and not by measuring Medicare DSH.

Comment: One commenter questioned whether CMS proposed accompanying documentation requirements with the proposed Evaluation Criteria on the CMS Evaluation Form. The commenter stated: "it seems that the attestation is all that is required for those hospitals that indicate on the application form that they meet one or more of the criteria…this proposal seems somewhat at odds with the proposed documentation requirements associated with the demonstrated likelihood criteria…"

Response: We disagree with the comments since we did propose documentation requirements accompanying the proposed evaluation criteria on the CMS Evaluation

Form. Among the requirements we proposed at 69 FR 28300-28301 that hospitals must meet to apply for the section 422 increase to the FTE caps is that the hospital must include: "[a] completed copy of the CMS Evaluation Form…for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the Evaluation Form. (For example, if the hospital checks off on the Evaluation Form that the hospital is located in a geographic Health Professions Shortage Area (HPSA), the hospital would include documentation to support that assertion**.)** (Emphasis added.) We are finalizing this proposed requirement, as stated in part here, in this final rule.

Comment: We received one comment asking CMS to clarify that a hospital which is within a level priority category and meets a Demonstrated Likelihood Criterion will be entitled to obtain residency slots before any hospital located in the next (that is lower) level priority category, even if the first hospital meets *none* of the Evaluation Criteria.

Response: As we explained above and also in the proposed rule, we are awarding section 422 cap increases first by level priority category, and then, within each level priority category, by points from the Evaluation Criteria on the CMS Evaluation Form, per hospital program. Thus, the commenter is correct; in the case where Hospital A qualified to be in level priority category one for a program, but scores no points on the Evaluation Criteria on the CMS Evaluation Form for that program, and Hospital B qualifies to be in level priority category two for a program, and scored 5 points on the Evaluation Criteria on the CMS Evaluation Form for a program, Hospital A will receive

the section 422 cap increase *before* Hospital B, because Hospital A qualified to be in the higher level priority category.

Comment: Two commenters believed that CMS should include consideration of children's hospitals among the evaluation criteria on the CMS Evaluation Form. Specifically, the commenters proposed that we add an evaluation criterion to give a point to hospitals that treat a "predominantly pediatric patient population." One commenter also proposed that we add another evaluation criterion to give another point for hospitals that treat "a high percentage of SCHIP [State Children's Health Insurance Program] beneficiaries or uninsured patients."

Response: While we appreciate the commenters' desire to add evaluation criteria and garner additional points for use by children's hospitals when applying to receive section 422 increases to their FTE resident caps, we note that there are already evaluation criteria in the proposed rule (all of which we are finalizing) that may be applicable to children's hospitals. For instance, a children's hospital may be rotating residents for at least 25 percent of the duration of the residency program to a rural area, a rural health clinic, or a federally qualified health center. Or, a children's hospital may be training displaced residents from a closed program, or training residents above its 1996 FTE cap because it was awaiting accreditation of a new program from the ACGME or AOA during the base period for its FTE cap(s), but was not eligible to receive a new program adjustment. In addition to these evaluation criteria, there are several others that children's hospitals may use when applying to receive an increase in their FTE resident

caps. Therefore, we are not adopting the commenter's proposal to add evaluation criteria specific to children's hospitals.

Comment: We received several comments on the proposed Evaluation Criterion Three, which states--

"C3: Evaluation Criterion Three. The hospital does not qualify for an adjustment to its FTE caps under existing §413.86(g)(12) for a rural track residency program, but is applying for an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act because it rotates (or in the case of a new program, will rotate) residents for at least 25 percent of the duration of the residency program to any one (or in combination thereof) of the following: a rural area, as defined in section 1886(d)(2)(D)(ii) of the Act and §412.62(f)(1)(iii) of the regulations; a rural health clinic (RHC), as defined in section 1861(aa)(1) of the Act and §491.2 of the regulations; or a Federally Qualified Health Center (FQHC), as defined in section 1861(a)(3) of the Act and §405.2401(b) of the regulations."

Several commenters applauded CMS for proposing this Evaluation Criterion Three. One of the commenters asked CMS to clarify whether this criterion would apply to residents in existing programs, and not just new ones.

Another commenter believed that for allopathic family practice residents, it would be a problem to rotate residents out of the hospital for a period of time greater than 3 months out of the program: "we believe the current threshold requirement of 25 percent time in the current evaluation criterion three is not in keeping with the best data available. 25 percent of time for a family practice training program is 9 months. Our data show that

only 3 months training time in rural areas is necessary to show large changes in outcomes. Since the family practice RRC also requires two years of continuity training with the same patient population, most programs, unless they are located in rural areas themselves, or are rural training tracks, cannot meet a 25 percent requirement. We request that this threshold be decreased to a commensurate percentage."

Response: We appreciate the commenters' support of proposed Evaluation Criterion Three. To respond to the first comment concerning whether the criterion would apply to *existing* residency programs that rotate residents for at least 25 percent of the duration of the program to those locations, we point to the language in the proposed criterion that says "because it rotates (or in the case of a new program, will rotate)." We believe we have included resident rotations for both new and *existing* residency programs.

In response to the second commenter, we understand the concerns of allopathic family practice programs that may have "continuity" problems from the RRC where residents are rotated outside of the hospital for 25 percent of the duration of the program, however, as noted in this final rule, we are specifically addressing family practice programs (that is, primary care programs) in Evaluation Criterion 11. Therefore, even if hospitals with family practice programs are not able to fulfill this particular Evaluation Criterion, they may be able to meet Evaluation Criterion 11, among possibly others.

Comment: One commenter addressed the proposed Evaluation Criterion Seven on the CMS Evaluation Form, which states--

"• C7: Evaluation Criterion Seven. The hospital is located in any one (or in combination thereof) of the following: a geographic HPSA, as defined in 42 CFR 5.2; a population HPSA, (also defined at 42 CFR 5.2); or a Medicare physician scarcity county, as defined under section 413 of Pub. L. 108-173."

The commenter believed that CMS should "continue with this idea, but broaden its approach to include time residents spend training in these areas, not just where the hospital is located." In addition, this commenter believed that CMS should have another evaluation criterion based upon where the graduates of a residency program go into practice. The commenter states: "[m]any worthwhile programs not located in rural or underserved designated areas produce a fair number of residents who locate their practices in such areas. As such, in keeping with the Congressional intent of this section of statute, it makes sense for CMS to award a priority point for those situations as well."

Response: We believe it would be duplicative to allow applicant hospitals to receive a point in the evaluation criteria for example rotating residents to a nonhospital setting that is located in a geographic or population HPSA or Medicare physician scarcity county, when the applicant hospitals already will receive a point in the evaluation criteria under Evaluation Criterion Three (as revised in this final rule) for rotating residents for a significant period to a rural area or a FQHC. Therefore, we are adopting the proposed Evaluation Criterion Seven as final.

To address the second comment concerning awarding a point based not on the location of the hospital, but on where the new graduates of programs have their practices, while we appreciate that hospitals believe they have increased the retention of physicians

to rural and underserved populations when residents train in their programs; however, it is difficult for the Medicare program to track such after-the program data for purposes of audit of where particular graduates work after finishing their training. Therefore, we are not adopting the commenter's suggestion concerning physician retention, as well.

Comment: We received one comment requesting that CMS add an Evaluation Criterion for hospitals that train ophthalmology residents. The commenter states that a high number of Medicare beneficiaries benefit from physicians in this specialty. In another comment, we received a request to address hospitals that train residents in palliative sub-specialty programs.

Response: Unlike geriatrics, primary care, and emergency medicine, we do not believe that the Congress has specified "ophthalmology residency training" or "palliative residency training" for special consideration within the Medicare statute, nor in any Conference Report language. While we believe both ophthalmology and palliative medicine provide services to Medicare patients, since physicians in these areas serve many individuals, not only Medicare beneficiaries, we do not agree to add a new Evaluation Criterion to the CMS Evaluation Form to address ophthalmology or palliative training.

Comment: We received one comment requesting that CMS add an Evaluation Criterion for any hospital that is a state operated public hospital. The commenter requests that, in the alternative, CMS "add an Evaluation Criterion for any hospital that is a (i) public hospital or (ii) the only public hospital in its MSA."

Response: While we believe that public hospitals serve an important role in health care, particularly, for medically underserved areas of this country, we do not agree to add a new Evaluation Criterion to the CMS Evaluation Form to address public hospitals, specifically. We believe that we may have addressed the needs of some public hospitals by many of the proposed Evaluation Criteria, and some of the new ones that we are finalizing in this final rule, as well. For instance, Evaluation Criteria Seven, which would address many hospitals located in a HPSA or a Medicare physician scarcity county may provide a point for some public hospitals. Other than the evaluation criteria, we do not believe it is appropriate to single out a hospital by type of ownership for special consideration.

Comment: One commenter described the situation of a hospital that is "in partnership" with a FQHC concerning a family practice program, where the FQHC is the sponsor of the residency program, and the hospital "passes through" every dollar in Medicare direct GME and IME payments the hospital receives to the FQHC, and the hospital was "caught" by the BBA-mandated caps. The commenter requested that CMS add a new evaluation criterion to the CMS Evaluation Form that addresses this situation.

Response: While we are sympathetic to the situation of hospitals clearly serving medically underserved populations (which is generally the case of a residency program that is sponsored by a FQHC), we believe that proposed Evaluation Criteria Three, Five, or Six may address the hospital described by the commenter. Therefore, we decline to address the situation described by the commenter with an Evaluation Criterion on the

CMS Evaluation Form in this final rule. However, we would encourage these hospitals to apply for the increase to the caps under section 422.

Comment: We received one comment on the proposed Evaluation Criterion Nine, which concerns awarding a point for hospitals "affiliated with a historically Black medical college." The commenter disagreed with the CMS proposed interpretation of the Conference Report language that accompanied Pub. L. 108-173, which stated that the Secretary should consider whether the hospital is a "historically large medical college" in evaluating hospital applications for the increase to their caps under section 422. In the proposed rule, we stated--"[u]pon consideration of this particular terminology, which, on its face, seems to contradict the three statutory priority categories (that is, rural, "small" urban, and only specialty program in the State), we proposed to view the reference to "historically large medical colleges" as a scrivener's error, and to read this language to refer to "historically Black medical colleges." This proposed interpretation accomplishes two goals--first, we believe this interpretation serves the greater policy goal of encouraging residency training for the benefit of medically underserved populations. Second, we believe that this interpretation reflects the Conferees' intent in the language in the Conference Report." The commenter believed that the CMS interpretation of the Conference Report terminology is "inaccurate and arbitrary…" and that historically large medical colleges" deserve special consideration as they play an important role in educating a large portion of medical students. In some cases these hospitals may be training at a level above their cap and deserve recognition for that."

Response: We believe our proposed interpretation of the term in the Conference Report, "historically large medical colleges," is appropriately interpreted to mean "historically Black medical colleges," as we explained in the proposed rule. We believe historically Black medical colleges serve an important role for medically underserved populations and we would like to award hospitals that train residents that are in programs sponsored by historically Black medical colleges. While we also agree with the commenter that "historically large medical colleges" play an important role in graduate medical education, we do not believe a literal reading of the report language can be consistent with Congress' explicit statement of priorities at section 1886(h)(7)(B) of the Act. In any case, we believe that we have addressed the issue of large medical college hospitals training residents above their FTE caps with other evaluation criteria addressed in this final rule.

Comment: We received one comment that requested CMS add an Evaluation Criterion for any hospital that has a Medicare Case Mix Index (CMS) greater than 1.70. The commenter believes: "[t]his is an indicator that the hospital is serving severely ill patients who most benefit from being treated in a teaching institution."

Response: We appreciate the commenter's suggested Evaluation Criterion, but we have chosen not to adopt it, since a criteria based on severity of illness in general is not necessarily a measurement of the need for additional residents in any specific program.

j. IME Adjustment Formula Multiplier for Redistributed FTE Resident Slots (Section 422(b)(1)(C) of Pub. L. 108-173) and the Application of Locality-Adjusted National Average Per Resident Amount (PRA)

Section 1886(h)(7)(B)(v) of the Act, as added by section 422 of Pub. L. 108-173, provides that, with respect to additional residency slots attributable to the increase in the hospital's FTE resident cap as a result of redistribution of resident positions, the approved FTE resident amount, or PRA, is deemed to be equal to the locality-adjusted national average per resident amount computed for that hospital. In other words, section 1886(h)(7)(B)(v) of the Act requires that, for purposes of determining direct GME payments for portions of cost reporting periods occurring on or after July 1, 2005, a hospital that receives an increase in its direct GME FTE resident cap under section 1886(h)(7)(B) of the Act will receive direct GME payments with respect to those additional FTE residents using the locality-adjusted national average PRA. Thus, in the May 18, 2004 proposed rule (69 FR 28305), we proposed that a hospital that receives an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act would receive direct GME payments based on the sum of two different direct GME calculations: one that is calculated using the hospital's actual PRAs (primary care PRA or nonprimary care PRA) applicable under existing §413.86(e)(4) (proposed to be redesignated as §413.77(d) in the proposed rule) and the hospital's number of FTE residents *not* attributable to an FTE cap increase under section 1886(h)(7)(B) of the Act; and another that is calculated using the locality-adjusted national average PRA under existing §413.86(e)(4)(ii)(B) (proposed to be redesignated as §413.77(d)(2)(ii) in the proposed rule) inflated to a

hospital's current cost reporting period, and the hospital's number of FTE residents that is attributable to the increase in the hospital's FTE resident cap under section 1886(h)(7)(B) of the Act.

Section 422(a) of Pub. L. 108-173 contains a cross-reference in the new section 1886(h)(7)(B)(v) of the Act to the locality adjusted national average PRA "computed under paragraph (4)(E)." However, section 1886(h)(4)(E) of the Act does not relate to the locality-adjusted national average PRA. Rather, it relates to the circumstances under which a hospital may count FTE resident time spent training in nonhospital sites.

We have concluded that the cross-reference to section 1886(h)(4)(E) of the Act is a legislative drafting error, or scrivener's error. Instead, we believe the Congress intended to refer to section 1886(h)(2)(E) of the Act, which explicitly provides for the determination of locality-adjusted national average PRAs. Because the drafting error is apparent, and a literal reading of the cross-reference as specified in the statute would produce absurd results, we proposed to interpret the cross-reference to section 1886(h)(4)(E) of the Act in the new section 1886(h)(7)(B)(v) of the Act as if the reference were to section 1886(h)(2)(E) of the Act.

We note that section 1886(h)(7)(B)(v) of the Act, which addresses the applicability of the locality-adjusted national average PRAs with respect to redistributed slots for the direct GME payment, makes no reference to section 1886(h)(4)(G) of the Act, which is the provision concerning the rolling average count of FTE residents. That is, the statute does not provide for an exclusion from application of the rolling average for residents counted as a result of FTE cap increases under section 1886(h)(7)(B) of the Act.

In light of the absence of a specific pronouncement in section 1886(h)(7)(B) of the Act exempting those residents from application of the rolling average, and with no apparent reason to treat residents counted as a result of the FTE cap increases under section 1886(h)(7)(B) of the Act differently for purposes of the rolling average, we had proposed to require that if a hospital increases its direct GME FTE count of residents as a result of an FTE resident cap increase under section 1886(h)(7)(B) of the Act, those FTE residents would be immediately subject to the rolling average calculation. Furthermore, we believed that, given potentially significant shifts of FTE slots among hospitals as a result of section 1886(h)(7) of the Act, the inclusion of FTE residents counted as a result of section 1886(h)(7)(B) of the Act in the rolling average would introduce a measure of stability and predictability, and mitigates radical shifts in direct GME payments from period to period.

Comment: We received several comments on the implementation of section 1886(d)(5)(B) of the Act as modified by section 422(b) of Pub. L. 108-173, concerning the reduction in the IME adjustment factor, and also section 1886(h)(7)(B)(iv) of the Act, as added by section 422 of Pub. L. 108-173, concerning the application of the locality adjusted national average PRA, when a hospital receives an increase to its FTE caps for IME and direct GME under section 422. One commenter objected to our application of these two statutory provisions. The commenter stated that "although we recognize that CMS does not have the authority to alter those formula defined in the statute, …[we] strongly believe that the Medicare reimbursement formula for all residency positions should be consistent and the section 422 of the [Medicare Modernization Act of 2003]

should not have mandated a locality-adjusted national average per resident amount and reduction in the IME factor."

Other commenters similarly had concerns with the CMS proposed application of the reduced payment rates required for the IME adjustment factor and the locality-adjusted national average PRA. Specifically, these commenters disagreed with the proposed implementation of the rolling average methodology and also the intern and resident to bed ratio (or "IRB") cap on IME payments, as stated in the proposed rule. The commenters disagreed with the "immediate" application of these two policies to the FTE cap adjusted under section 422. One commenter stated that applying the IRB cap as proposed "…effectively reduces a hospitals IME payments below the 50 percent level, and possibly to zero for the first year, and the 3-year rolling average which results in a 3 year phase-in causes additional IME payment delays for these redistributed residents. We believe this IME payment provision as proposed makes it much more difficult for providers to obtain and maintain board approval for commitment of new residency programs when CMS is not even proposing payments at 50 percent of their standard IME payment levels for these redistributed residents." The commenter asked that CMS reconsider the application of the rolling average and the IRB cap to the section 422 FTE increase.

Another commenter, also in support of CMS excepting the application of the rolling average and the IRB cap to the section 422 increase, reminded us that "in the past, CMS [has] created exceptions to the application of the rolling average and the [IRB] cap when there were compelling reasons to do so, even in the absence of a statutory

mandate." The commenter gave the examples of the initial years of the new residency program adjustment to the 1996 caps as provided under §413.79(e) (formerly §413.86(g)(6)), and the temporary adjustment to the 1996 caps from residents that are displaced from program or hospital closure, as provided under redesignated §413.79(e) (formerly §413.86(g)(6)). This commenter also pointed out that it would be a "double penalty" to finalize the rolling average and IRB cap policy as proposed--"the first penalty being a payment rate penalty and the second penalty being an inability to count the residents fully in the first and second years."

In addition, another commenter asked CMS to consider providing a 3-year exemption from the rolling average for IME and direct GME and also the IRB cap for IME payments for any FTEs added as a result of section 422, in a manner similar to the new residency program adjustment to the FTE caps, which allows hospitals to except residents from the rolling average that are in the "initial years" of the new program. The commenter stated that "the current proposed policy [of immediate application of the rolling average and the IRB cap] . . . makes it unnecessarily difficult for qualifying rural and small city hospitals to properly take advantage of the redistribution process."

Response: We appreciate hospitals' concern with the complexity of receiving different direct GME and IME payments for the residency slots received as per section 422 and the "regular" direct GME and IME payments for the residency slots counted within the hospitals' 1996 FTE caps on the count of residents in accordance with sections 1886(d)(5)(B) and (h)(4) of the Act. As the first commenter correctly states, section 422 of Pub. L. 108-173 mandates different direct GME and IME payments for the increased

slots received under section 422, and CMS has no discretion but to implement these two provisions as written. Due to the complex nature of the different payments for the different FTEs ("section 422 FTEs" and "1996 cap FTEs"), we will refer to the increase a hospital receives in its 1996 FTE cap under section 422 as "the section 422 cap" for purposes of direct GME and IME payments. The section 422 cap will be labeled as such on Worksheets E, Part A and Worksheets E-3, Part IV on the Medicare cost report so that both hospitals and the fiscal intermediaries will be able to more easily determine the different direct GME and IME payments for the different FTEs, depending on whether the FTE residents trained at the hospital are within the hospital's adjusted 1996 FTE cap, or are above that adjusted 1996 FTE cap and, therefore, subject to a section 422 cap.

To address the comments concerning the proposed immediate application of the rolling average to FTEs counted within the section 422 cap for purposes of direct GME and IME payments, and the application of the IRB cap to section 422 FTEs counted for purposes of IME payments, we agree with the commenters that the proposal could create a disincentive for hospitals to apply for the increase to their caps under section 422 because of the "extra-reduced" direct GME and IME payments that would result from the application of the IRB cap and rolling average in the initial years of counting the FTEs within the section 422 caps. We are also concerned that the proposed immediate application of the rolling average and the IRB cap may, as one commenter put it, make it "much more difficult for providers to obtain and maintain board approval for commitment of new residency programs." Furthermore, we believe that the application of the IRB cap and rolling average to residents counted within the section 422 caps would

add significantly to the administrative burdens of both hospitals and fiscal intermediaries to track these residents for purposes of the differing payment rates for IME and direct GME. For these reasons, effective for portions of cost reporting periods and discharges beginning on or after July 1, 2005, CMS will not include the FTEs counted within the section 422 cap in the 3-year rolling average calculation for purposes of direct GME and IME payments. In addition, effective with discharges on or after July 1, 2005, CMS will not apply the IRB cap to the FTEs counted within a hospital's section 422 cap, for purposes of IME payment.

Although one commenter suggested a 3-year exception to the IRB cap and the rolling average, we agree with the commenters that argued that it is appropriate to not apply either of these limitations on the reduced payment authorized by section 1886(h)(7) of the Act.

Because the policies stated above are changed from those stated in the proposed rule at 69 FR 28283 for IME and 69 FR 28305 for direct GME, we provide the following two examples to clarify how the calculations for the payments will work when FTEs are counted within a hospital's section 422 cap:

Example 1: IME adjustment factor

This example illustrates how the IME adjustment factor would be calculated for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. Hospital A has a fiscal year end (FYE) of September 30, and a 1996 IME FTE cap of 20 FTEs. During its FYEs September 30, 2003, September 30, 2004, and September 30, 2005, Hospital A trains 25 FTE residents.

Effective for discharges beginning on or after July 1, 2005, under section 1886(h)(7)(B) of the Act, Hospital A receives an increase to its IME cap of 5 FTEs. These additional 5 FTEs are the hospital's IME section 422 cap. The hospital now has an IME 1996 cap of 20 FTEs and an IME section 422 cap of 5 FTEs. Hospital A has maintained an available bed count of 200 beds for FYE September 30, 2004 and continuously through FYE September 30, 2005. The IME adjustment factor formula multiplier for discharges occurring during FY 2005 is 1.42 (as required by section 502(a) of Pub. L. 108-173). The IME adjustment factor formula multiplier for redistributed FTE resident slots is .66 (set by section 422(b)(1)(C) of Pub. L. 108-173). For the FYE September 30, 2005 cost report, the IME adjustment factor is calculated as follows:

Step 1: For discharges occurring October 1, 2004, through September 30, 2005, for residents counted but NOT pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Rolling average count of FTE residents: 20+20+20/3=20
- Current year resident-to-bed ratio: 20/200=.10.
- Cap on resident-to-bed ratio (from prior year): 20/200=.10.
- Compare, and use the lower of, prior year resident-to-bed and current year resident-to-bed ratio: .10 = .10.
- Compute IME adjustment factor for FTE residents counted in the 1996 cap: $1.42 \times [\{1+.10\}^{.405} - 1] = 0.0559$

Step 2: For discharges occurring on July 1, 2005 through September 30, 2005 for residents counted as part of the section 422 cap pursuant to section 1886(d)(5)(B)(ix) of the Act:

- Resident-to-bed ratio for 7/1/05 – 9/30/05: 5/200=.025
- Compute IME adjustment factor related to the section 422 cap:

$0.66 \times [\{1+.025\}^{.405}-1] = 0.0066$

Step 3: Compute the combined IME adjustment factor for the hospital (attributable to both the 1996 cap and the section 422 cap):

- For discharges occurring October 1, 2004, through June 30, 2005, the IME adjustment factor for the hospital is 0.0559 (Step 1).
- For discharges occurring July 1, 2005 through September 30, 2005, the combined IME adjustment factor for the hospital is 0.0625 (that is, 0.0559 + 0.0066) (Step 1 + Step 2).

Since the additional FTEs counted within the section 422 cap are not in the 3-year rolling average calculation or subject to the IRB cap, Hospital A is able to add 0.0066 to the IME adjustment factor for discharges occurring July 1, 2005, through September 30, 2005.

Example 2: Direct GME payment

This example illustrates how the direct GME payment would be calculated for a hospital that receives an increase to its FTE resident cap as a result of section 1886(h)(7)(B) of the Act. For example, Hospital B has a fiscal year end (FYE) of June 30, and a 1996 direct GME FTE cap of 20 FTEs. During its FYEs June 30, 2004 and June 30, 2005, Hospital B trained 20 nonprimary care residents. During FYE June 30, 2006, Hospital B trains 25 nonprimary care FTE residents. Hospital B's FYE June 30, 2006 nonprimary care PRA is $100,000. The FYE June 30, 2006 locality-adjusted national average PRA for Hospital B is $84,000. Hospital B's Medicare utilization is 35 percent in FTE June 30, 2006. Effective July 1, 2005, under section 1886(h)(7)(B) of the Act, Hospital B receives an increase to its direct GME cap of 5 FTEs. These additional 5 FTEs are the hospital's direct GME section 422 cap. The hospital now has a direct GME 1996 cap of 20 FTEs and a direct GME section 422 cap of 5 FTEs. For the FYE June 30, 2006 cost report, the direct GME payment is calculated as follows:

Step 1: For residents counted but NOT pursuant to section 1886(h)(7)(B) of the Act:

- Rolling average count: 20+20+20/3 = 20.
- Direct GME computation: $100,000 x 20 x .35 = $700,000.

Step 2: For residents counted pursuant to section 1886(h)(7)(B) of the Act (the section 422 cap):

- Direct GME computation: $84,000 x 5 x .35 = $147,000.

Step 3: Total direct GME payment for FYE June 30, 2006: $700,000 + $147,000 = $847,000.

Comment: One commenter stated that the calculation of the IME payment relating to additional residents counted as a result of an increase in the hospital's FTE cap received under section 1886(h)(7)(B) of the Act is extremely cumbersome and will require difficult and extensive changes to the Medicare cost report, particularly if the additional residents are to be subject to the rolling average and the resident-to-bed ratio. The commenter suggested that instead of revising Worksheet E, Part A to include this calculation, CMS should consider including this calculation on a separate worksheet, with the results added to Worksheet E, Part A.

Response: First, we note that we are required by section 1886(d)(5)(B)(ix) of the Act to apply a different IME formula multiplier to calculate the IME payment relating to these residents. Therefore, some level of additional complexity is not avoidable. Additionally, we have stated in previous responses concerning the IME calculation relating to residents counted under section 1886(h)(7)(B) of the Act, under our final policy, we are not requiring that these residents be subject to the rolling average and resident-to-bed ratio calculations. Thus, we believe that our final policy substantially reduces the complexity of the proposed calculations that concerned the commenter. Even so, we do realize that the presence of an additional calculation on Worksheet E, Part A for IME (and also on Worksheet E-3, Part IV for direct GME) further complicates an already difficult calculation. We will attempt to revise the worksheets in the simplest and least disruptive manner.

Comment: One commenter discussed the situation of a hospital that was subject to the reductions as required under section 1886(h)(7)(A) of the Act because it was below its 1996 FTE cap, that also applies for the cap increase (that is, the section 422 cap) as provided under section 1886(h)(7)(B) of the Act. The commenter believed that only the "aggregate" FTE amount, that is, the difference in number of positions between the reduction in the cap and the cap increase, both provided under section 422, should be the sole basis for the application of the reduced direct GME and IME payment rates. Using the commenter's reasoning in an example, there is Hospital A, which has a 1996 FTE cap of 100 FTEs on June 30, 2005. Hospital A's resident FTE cap is raised to110 FTEs as of July 1, 2005 under the section 422 increase. Under the section 422 reductions, Hospital A's cap was lowered to 90 FTEs, also as of July 1, 2005. As per the commenter's proposal, CMS would apply the reduced direct GME and IME payment rates only to 10 FTEs for Hospital A, because 10 FTEs is the difference in number of positions between Hospital A's reduction in the cap and Hospital A's cap increase. Thus, the commenter suggested that, in the situation of a hospital that was reduced under section 422 for a greater number of FTEs than the hospital received as a section 422 cap, there would be no "redistributed" residents and, thus, there would be no application of the reduced payment rates.

Response: We do not agree with the commenter's suggestion. We believe that sections 1886(h)(7)(A) and (B) of the Act--the section 422 reduction and increase provisions, respectively--are two very different processes that require separate determinations by CMS. The only connections between subparagraphs (A) and (B) are

that the cap increases through (B) are made by us through an estimated pool of FTE slots gathered from the reductions made through (A), and that both the reductions under (A) and the increases under (B) are effective July 1, 2005. The similarities end there. We believe the reductions and the increases are stand-alone provisions and that the Congress did not intend that we would use the difference in the number of positions between the reduction in the cap and the cap increase, both provided under section 422, as the "sole basis" for the application of the reduced direct GME and IME payment rates, as the commenter suggested. We believe that a "redistribution" under section 1886(h)(7)(B) of the Act is simply an increase to the adjusted 1996 cap, as reduced where applicable by section 1886(h)(7)(A) of the Act. It is not the difference between the section 422 reduction and the section 422 increase for any one applicant hospital.

Other Issues on the Request for Increase in the FTE caps under Section 422

Comment: One commenter requested that CMS clarify the question of whether rural hospitals that establish a new residency program are precluded from receiving a new residency program adjustment under §413.86(g)(6)(i) (redesignated as §413.79(e)(1)), if the hospitals can also receive an increase to their FTE caps if they apply under section 422. Similarly, another commenter stated that for expansion of rural programs up to 130 percent of their BBA-set cap, it should be made clear that CMS' proposals concerning section 422 do not supersede the BBRA provision, but are in addition to it, "so a rural hospital that wishes to increase its BBA-set cap, may do so up to 130 percent, and may of course use this provision for any positions beyond that number." Finally,

several commenters asking CMS to exclude applicant hospitals from consideration under section 422 if they are eligible for current regulatory exceptions to the 1996 FTE caps.

Response: Rural hospitals may receive an adjustment to their FTE caps for establishing a new residency program under redesignated §413.79(e)(1)), at any time, and are not precluded from requesting the new residency program adjustment even if the hospitals also receive an increase to their FTE caps under section 422. However, we note that hospitals, rural or urban, may not apply for a permanent adjustment to their FTE caps under current Medicare regulations and also apply for an increase to their FTE caps under section 422 for the same new residency program. Though, such hospitals may apply for an increase under section 422 for a different residency program(s).

In response to the second commenter's suggestion, there is nothing that precludes a rural hospital from requesting an increase to its FTE cap under section 422 even if it also received a 130 percent expansion under the BBRA of 1999. We do not believe that when the Congress enacted section 1886(h)(7)(B) of the Act, it intended to limit rural hospital from receiving any additional slots. In fact, the Congress gave rural hospitals priority in the redistribution process.

Comment: One commenter asked whether CMS plans to provide oversight of a hospital's section 422 caps. Specifically, the commenter wanted to know if hospitals could use the FTE cap increase as per section 422 for any program at the applicant hospital, "in spite of receiving them on the basis of demand for starting or expanding a specific specialty program."

Response: As we stated above, once a hospital receives its section 422 cap after applying for the increase as stated in this final rule, beginning July 1, 2005, the section 422 cap is applied to FTEs in any program that the hospital is training in excess of its 1996 FTE cap, regardless of the hospital's program-specific basis for being granted the section 422 cap.

However, we note that, in order to qualify to apply for the increase to its FTE caps under section 422, a hospital must fulfill the demonstrated likelihood criteria on the CMS Evaluation Form (as finalized in this rule). The hospital must complete a CMS Evaluation Form for each residency program for which the hospital requests a FTE cap increase. In addition to a CMS Evaluation Form(s), the hospital must include as part of its application for the section 422 caps an attestation to the truth and veracity for the information included in the hospitals application. Thus, while the section 422 cap is an aggregate non-program-specific cap, when we determine which hospitals are to receive the section 422 caps, we are basing our determinations on the program-specific information provided by the hospital at the time of the hospital's application.

Comment: Two commenters asked whether both the requests for the increases in the IME cap and the direct GME cap could be on the same hospital application for the section 422 caps.

Response: As we stated above and also in the proposed rule, as part of the requirements that a hospital must fulfill in order to complete an application for the section 422 caps, is the requirement that the applicant hospital must include the total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME

or IME, or both (up to 25 FTEs). Thus, both of the increases in the IME and the direct GME cap request (that is, the total number of requested FTE resident slots (for all residency programs at the hospitals)) are required to be on the same hospital application for the section 422 caps.

As stated above, a hospital must submit the following in order to apply for the section 422 caps:

- The name and Medicare provider number of the hospital.
- The total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME or IME, or both (up to 25 FTEs).
- A completed copy of the CMS Evaluation Form for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the Evaluation Form.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report.
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information in the hospital's application for an increase in its FTE resident cap:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured

through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

Comment: One commenter asked why the "resident cap redistribution process" is not included in the proposed regulations text, and that only "summary information" is provided under proposed §413.79(c)(4).

Response: We proposed only "summary information" at proposed §413.79(c)(4) because the process for applying for the section 422 caps is a one-time process, not to be repeated, as we understand it. We see no reason to put in all of the steps for applying for the section 422 caps into regulations, as well as our evaluation process of the applications. There may be some hospitals that will apply for the section 422 caps, and other hospitals that will not apply. However, to avoid any misunderstanding as to the process for applying for the section 422 caps, in this final rule, we are revising §413.79(c)(4) to state ,"For portions of cost reporting periods beginning on or after July 1, 2005, a hospital may receive an increase in its otherwise applicable FTE resident cap up to an additional 25 FTEs (as determined by CMS) if the hospital meets the requirements and qualifying criteria of section 1886(h)(7) of the Act and implementing instructions issued by CMS, including the preamble to the **[OFR insert the date of**

publication], and if the hospital submits an application to CMS within the timeframe specified by CMS.".

k. Application of Section 422 to Hospitals that Participate in Demonstration Projects or Voluntary Reduction Programs

Section 1886(h)(7)(B)(vi) of the Act, as amended by section 422(a)(3) of Pub. L. 108-173, states that "Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs . . . under a demonstration project approved as of October 31, 2003." This language is referring to the New York Medicare GME Demonstration Project and the Voluntary Resident Reduction Project (VRRP) under section 402 of Pub. L. 90-248. In July 1997, 42 New York teaching hospitals participated in the demonstration project. As there were two entry points for this demonstration, an additional seven hospitals joined the program in July 1998. The purpose of the demonstration project was to test reimbursement changes associated with residency training to determine whether hospitals could use time-limited transition funding to replace and reengineer the services provided by a portion of their residency trainees. In exchange for reducing its count of residents by 20 to 25 percent over a 5-year period, while maintaining or increasing its primary care-to-specialty ratio of residents, a participating hospital (or consortium of hospitals) would receive "hold harmless payments" for 6 years. These payments represented a declining percentage of the Medicare GME reimbursement the participating hospitals would have received had their number of residents not been reduced.

For hospitals that successfully completed the demonstration project, the Balanced Budget Act of 1997 states that if a hospital increases the number of full-time equivalent residents permitted under its reduction plan as of the completion of the plan, it is liable for repayment of the total amounts paid under the demonstration. Following the demonstration's period of performance, which ended June 30, 2003, if a hospital exceeds its post-demonstration cap and trains residents in excess of the FTE levels achieved under the demonstration, the hospital is not permitted to count those excess residents for purposes of Medicare GME payments until such time as the hold harmless funds paid under the demonstration project have been repaid in full.

Similarly, with the VRPP, hospitals could use time-limited transition funding to replace the services provided by a portion of their residents. In exchange for reducing its count of residents by 20 to 25 percent over a 5-year period, while maintaining or increasing its primary care-to-specialty ratio of residents, a VRRP participating hospital would receive "hold harmless payments" for 5 years. These payments represented a declining percentage of the Medicare GME reimbursement the VRRP participating hospital would have received had its number of residents not been reduced.

In the May 18, 2004 proposed rule, we indicated that we believe that the language of section 1886(h)(7)(B)(vi) of the Act precludes the Secretary from redistributing residency positions that are unused due to a hospital's participation in a demonstration project or the VRRP to other hospitals that seek to increase their FTE resident caps under section 1886(h)(7)(B)(i) of the Act. That is, if we were to specify that hospitals that participated in a demonstration project or the VRRP are subject to possible reductions to

their FTE resident caps under section 1886(h)(7)(A)(i) of the Act, any excess slots resulting from reductions made under section 1886(h)(7)(A)(i) of the Act attributable to the demonstration or the voluntary reduction program at these hospitals would not be allocated to the resident pool and redistributed to other hospitals. We also believed that section 1886(h)(7)(B)(vi) of the Act is silent as to whether the Secretary should apply the possible reductions under section 1886(h)(7)(A)(i) of the Act to the FTE resident caps of these hospitals. The Congress recognized the unique status of reductions in FTE resident counts made by these hospitals that participated in a demonstration project under the authority of section 402 of Pub. L. 90-248, or a VRRP under section 1886(h)(6) of the Act, in which these hospitals received hold-harmless payments from Medicare for reducing the number of residents that they were training. Accordingly, in the May 18, 2004 proposed rule (69 FR 28306), we proposed to recognize the unique status of FTE reductions made by these hospitals, and to apply the discretion that the Congress granted the Secretary under section 1886(h)(7)(A)(ii) of the Act in determining the reference resident level applicable to these hospitals, to determine the extent to which section 1886(h)(7)(A)(i) of the Act applies to these hospitals.

We note that section 1886(h)(7)(B)(vi) of the Act only applies to these hospitals to the extent that a hospital's "reductions in residency positions" were "attributable" to its participation in the demonstration project or the VRRP. In determining the reference resident level for these hospitals, we proposed to adjust the reference resident level for "reductions in residency positions attributable" to participation in the demonstration project or the VRRP. We proposed to define "reductions in residency positions

attributable" to participation in the demonstration project or the VRRP as the difference between the number of unweighted allopathic and osteopathic residents training at the hospital at the start of a hospital's participation in the demonstration project or the VRRP, (that is, the base number of residents as defined by the terms of the demonstration project and the VRRP,) and the number of such residents training at the hospital in the hospital's most recent cost reporting period ending on or before September 30, 2002. We proposed that, in determining any possible adjustments to the reference resident level for hospitals that participated in the demonstration project or the VRRP, we would differentiate between hospitals that withdrew from participation prior to the beginning of the most recent cost reporting period ending on or before September 30, 2002, and hospitals that either have not withdrawn from participation, or withdrew sometime during or after the most recent cost reporting period ending on or before September 30, 2002.

Specifically, we proposed that, if a hospital was participating in the demonstration project or the VRRP at any time during the hospital's most recent cost reporting period ending on or before September 30, 2002, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. If the higher of the base number of residents or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, is still less than the otherwise applicable FTE resident cap, we proposed to reduce the hospital's FTE resident cap amount by 75 percent of the difference, effective July 1, 2005. We also proposed to

use those slots in the redistribution process under section 1886(h)(7)(B) of the Act since those slots are not "attributable" to participation in the demonstration project or the VRRP.

Under section 1886(h)(7)(A)(ii)(II) of the Act, a hospital may submit a timely request to use its cost report that includes July 1, 2003, for purposes of determining the reference resident level if the hospital has an expansion of an existing program that is not reflected on the hospital's most recent settled cost report. If a hospital that was still participating in the demonstration project or the VRRP at some time during its most recent cost reporting period ending on or before September 30, 2002, had an expansion of an existing program that is not reflected on its most recent settled cost report, and the resident level for its cost reporting period that includes July 1, 2003, is higher than the resident level for the most recent cost reporting period ending on or before September 30, 2002, and is higher than the base number of residents, we anticipate that the hospital would submit a timely request that its resident level from its cost reporting period that includes July 1, 2003, be compared to its otherwise applicable FTE resident cap, for purposes of determining a possible reduction to the hospital's FTE resident cap. We believe that under the proposed policy discussed above, a hospital would only request that we utilize its cost reporting period that includes July 1, 2003, if the number of allopathic and osteopathic residents it trained in that cost reporting period is higher than its base number of residents and its base number of residents is less than its FTE resident cap. If we grant the hospital's request that we utilize its cost reporting period that includes July 1, 2003, and the resident level for that period is less than the FTE resident

cap, we would reduce the FTE resident cap by 75 percent of the difference between the two numbers. We also proposed to use those slots in the redistribution process under section 1886(h)(7)(B) of the Act, because those slots are not "attributable" to participation in the demonstration project or the VRRP.

If a hospital withdrew from participation in the demonstration project or the VRRP prior to its most recent cost reporting period ending on or before September 30, 2002, we proposed that such a hospital would be subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps. However, we note that such a hospital may still apply for an increase to its FTE caps as specified under section 1886(h)(7)(B) of the Act (the proposals for applying for the increase are described above).

Comment: One commenter was appreciative of the fact that CMS acknowledged that section 1886(h)(7)(B)(vi) of the Act only applies to hospitals that participated in the demonstration project to the extent that a hospital's "reductions in residency positions" were attributable to its participation in the demonstration project, and that, in determining the reference resident level for these hospitals, CMS proposed to adjust the reference resident level for reductions in residency positions attributable to participation in the demonstration project. The commenter supported our proposal that, for a hospital that was participating in the demonstration project during the most recent cost reporting year ending on or before September 30, 2002, CMS would compare the higher of the hospital's base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise

applicable FTE resident cap. However, the commenter requested that CMS expand upon its proposal to allow additional hospitals that do not meet the proposed criteria to demonstrate that certain reductions were also "attributable" to their participation in the demonstration project and, therefore, should be exempt from reduction to their FTE resident caps, for the following reasons: First, some hospitals withdrew prior to their most recent cost reporting period ending on or before September 30, 2002, because they realized that remaining in the demonstration project and maintaining reduced resident counts would compromise their educational and patient care missions in the long run. Second, because the terms and conditions of the demonstration project " 'front-loaded' the hold harmless payments by means of a declining percentage of the hospital's usual Medicare GME reimbursement, all demonstration hospitals gained incentivized to make as large a reduction as possible in the early years of the demonstration project." The commenter noted that, while some hospitals that withdrew prior to their most recent cost reporting period ending on or before September 30, 2002, were able to rebuild their residency programs close to or at the pre-demonstration project level, other hospitals have only just begun or are still in the planning stages for rebuilding their programs. The commenter further stressed the point that section 1886(h)(7)(B)(vi) of the Act, which prohibits the redistribution of reductions in residency positions attributable to voluntary reduction programs, does not specify a timeframe within which those hospitals need to refill those positions, and that, therefore, CMS should not impose such a criterion that differentiates between hospitals that withdrew from participation prior to the beginning of the most recent cost reporting period ending on or before September 30, 2002, and

hospitals that either have not withdrawn from participation, or withdrew sometime during or after the most recent cost reporting period ending on or before September 30, 2002.

The commenter recommended a multi-part criterion for hospitals that withdrew prior to the most recent cost reporting period ending on or before September 30, 2002, to demonstrate that particular resident reductions were attributable to the demonstration project and should be exempted from redistribution. The criterion focused on a two-part test for exemption from redistribution: hospital eligibility and residency program eligibility. The commenter suggested that a residency program's eligibility for consideration under the second-level criterion would be dependent on a hospital's satisfaction of the first-level criterion.

The commenter proposed that a hospital would have to meet the following criteria to prove the "first level criterion" for hospital eligibility:

- The hospital participated in demonstration project and withdrew prior to the most recent cost reporting period ending on or before September 30, 2002;
- The hospital's resident FTE count declined between the demonstration project base year and the point at which the hospital withdrew from the demonstration project; and
- The hospital's applicable FTE resident count in the hospital's reference resident level year is below both the hospital's demonstration project base year FTE resident count and the hospital's otherwise applicable FTE resident cap number.

The commenter proposed that the hospital would have to meet the following criteria to prove the "second level criterion" of residency program eligibility:

- The residency program was in operation during the base year for the demonstration project.

- The FTE resident count for that particular residency program declined between the demonstration project base year and the point at which the hospital withdrew from the demonstration project.

- The FTE resident count for that particular residency program in the hospital's reference resident level year is below both (a) the FTE resident count for that particular residency program during the base year for the demonstration project, and (b) the FTE resident count for that particular residency program during the most recent cost reporting period ending on or before December 31, 1996.

While the commenter believed that satisfaction of these two criteria prove that these reduced resident positions are attributable to demonstration project and should be exempt from redistribution, the commenter indicated that it would be pleased to work with CMS to develop basic documentation requirements to support the exemption should CMS believe such a requirement is needed. The commenter also noted that hospitals that withdrew from the demonstration project prior to the most recent cost reporting period ending on or before September 30, 2002, might have, in certain instances, added resident positions in departments other than where resident reductions attributable to the demonstration project were made. Therefore, in order to ensure that the number of individual reduced residency position eligible for exemption does not exceed the appropriate number of positions, the number of exemptions should be "capped" at the difference between (i) the number of FTE residents in the hospital's reference resident

level year, and (ii) the lower of the hospital's demonstration project base year FTE resident count and the hospital's otherwise applicable FTE resident cap number.

The commenter concluded that it recognizes that CMS may not be able to address all details of its recommended methodology in the final rule, and expressed hope that time constraints would not preclude CMS from giving ample consideration to the reasonableness of its recommendation and its consistency with the relevant provisions within section 422 of Pub. L. 108-173.

Response: As we explained in the May 18, 2004 proposed rule, while we believe that the language of section 1886(h)(7)(B)(vi) of the Act concerning hospitals that participated in the New York Medicare GME demonstration project or the VRRP precludes the Secretary from redistributing residency positions that are unused due to a hospital's participation in a demonstration project or the VRRP to other hospitals that seek an increase in their FTE resident caps under section 1886(h)(7)(B)(i) of the Act, we also believe that section 1886(h)(7)(B)(vi) of the Act is silent as to whether the Secretary should apply the possible reductions under section 1886(h)(7)(A)(i) of the Act to the FTE resident caps of these hospitals. As the commenter noted, we proposed that, in determining the reference resident level for these hospitals, we would adjust the reference resident level for reductions in residency positions attributable to participation in the demonstration project or the VRRP. In making this proposal, we considered the potential operational difficulties that would be imposed on both hospitals and the fiscal intermediary if we were to require that each hospital document reductions attributable to the demonstration project, whether at the hospital level, or at the program level. Thus, to

avoid undue administrative burden, and in absence of a clearly specified timeframe or cut off point for reductions attributable to participation in the demonstration or the VRRP in section 1886(h)(7)(B)(vi) of the Act, we proposed to use the hospital's most recent cost reporting period ending on or before September 30, 2002, which is the cost reporting period the Secretary is first directed to use under section 1886(h)(7)(A)(ii) of the Act, to determine any possible adjustments to the reference resident level for hospitals that participated in the demonstration project or the VRRP. Specifically, we proposed to differentiate between hospitals that withdrew from participation prior to the beginning of the their most recent cost reporting period ending on or before September 30, 2002, and hospitals that either have not withdrawn from participation, or withdrew sometime during or after their most recent cost reporting period ending on or before September 30, 2002. We believe it is necessary to establish a timeframe for a hospital's participation in a demonstration or VRRP because, at some point after withdrawal, it can no longer be said that reductions in the number of FTE residents are attributable to participation in a demonstration or VRRP. We believe that using the most recent cost reporting period ending on or before September 30, 2002, as the delineator for determining which hospitals may receive possible adjustments to their reference resident levels was clear, administratively feasible, had basis in the statute, and would be a reasonable reflection of which reductions were attributable to participation in a demonstration or VRRP. Therefore, we strongly disagree with the commenter's assertion that our proposed use of this cost reporting period was a "bright line" distinction that implied that there was some "predetermined maximum amount of time" for hospitals that participated in a

demonstration project to refill their vacated resident positions. In fact, those hospitals could refill, or not refill, those slots as they saw fit. Furthermore, to the extent that a hospital (involved in the demonstration project or otherwise) may have planned to increase its resident counts in the future, these plans are not recognized under section 1886(h)(7)(A) of the Act, which requires 75 percent of any "unused" slots must be "redistributed." The Congress did, however, recognize the unique status of reductions in FTE resident counts attributable to a hospital's participation in a demonstration project or the VRRP in the statute at section 1886(h)(7)(B)(vi) of the Act. Therefore, we do not believe our proposal would allow resident positions to be redistributed in "some wholesale manner," as the commenter suggested.

However, we do acknowledge the commenter's comprehensive and clearly articulated recommended methodology for documenting, both at the hospital level, and at the program-specific level, that select unused resident positions were attributable to the demonstration project, and should be exempted from redistribution. We note that hospitals, including those that participated in the demonstration, may reduce their FTE resident counts for many possible reasons. Thus, it would be impossible to determine with certainty, under any possible methodology, that a particular reduction in the number of FTE residents is purely attributable to participation in the demonstration or VRRP. Although we have considered various ways of documenting reductions in FTE resident counts attributable to participation in the demonstration project, we decided that any possible improvement in the definition of "attributable to" reductions would be offset by the difficulty for hospitals to produce this detailed, program-specific documentation, and

the significant additional audit workload that would be imposed on the fiscal intermediary. In addition, we note that the commenter's suggested methodology seems to focus solely on reductions in resident positions that occurred in specific programs between the time that the hospitals *entered* the demonstration project and the time that they *withdrew*. We believe a more credible method of demonstrating that reductions should be exempt from redistribution would be to document what has happened in those programs since the time that the *hospital* withdrew from the demonstration project, especially for those hospitals that ended participation in the demonstration in earlier years, and have had more time to add back to their FTE resident count those reductions that were solely attributable to participation in the demonstration. We believe evidence that the hospital's resident counts have grown since its withdrawal more convincingly advocates for an exemption from reduction for those resident slots, as opposed to emphasis on the number of slots that had been reduced prior to withdrawal. Thus, while we considered the commenter's recommendation that the hospitals should be required to supply program-specific information from the reference cost reporting period, the base year for the demonstration project, and for the most recent cost reporting period ending on or before December 31, 1996, we are not inclined to impose such detailed documentation requirements for the purpose of determining which of a hospital's reductions in FTE resident counts are attributable to participation in the demonstration project, and we question whether this data could necessarily be conclusive. Accordingly, we are not adopting the commenter's suggested multi-part methodology.

However, in light of the comments, and after reviewing the proposed policy, we have decided that, in finalizing our policy, we will further consider the length of time a hospital participated in the demonstration project or the VRRP before it withdrew. Specifically, we will provide the same protection that we proposed for hospitals that were still participating in the demonstration project during the cost reporting period ending on or before September 30, 2002, to hospitals that withdrew prior to that cost reporting period *if* the period of time the hospital participated in the demonstration project is longer than the period of time the hospital has been withdrawn from the demonstration project. For instance, the maximum amount of time that a hospital entering the demonstration project in 1997 could participate in the demonstration project was 6 years (from July 1997 to June 2003). A hospital that participated in the demonstration for *more than* 3 years would necessarily have participated in the demonstration for more years than it did not (that is, it would have been withdrawn from the demonstration for less than 3 years). We note that, for those hospitals entering the demonstration project at the second entry point in 1998, the maximum amount of time those hospitals could participate in the demonstration project was 5 years. If a hospital participated in the demonstration for a greater period of time than the time period that has elapsed since it withdrew from the demonstration project, we acknowledge that the hospital may not have had a sufficient amount of time to refill its residency slots to its base year level by its cost report that includes July 1, 2003. Therefore, in this final rule, we are finalizing our policy with respect to hospitals that participated in a demonstration project or the VRRP to state that, if a hospital participated in the demonstration project or the VRRP for a <u>longer</u>

period of time than it has been withdrawn from the demonstration project or the VRRP, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's allopathic and osteopathic base number of residents for the demonstration project or the VRRP, or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. If the higher of the allopathic and osteopathic base number of residents or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, is still less than the otherwise applicable FTE resident cap, we would reduce the hospital's FTE resident cap amount by 75 percent of the difference, effective July 1, 2005. We will also include those cap reductions in the redistribution process under section 1886(h)(7)(B) of the Act because those reductions are not "attributable" to participation in the demonstration project or the VRRP.

Although hospitals that participated in the demonstration project for less time than they have been withdrawn from the demonstration project may also have reduced their FTE resident counts at one point, we believe that those hospitals (particularly those that withdrew from the demonstration project after realizing, as the commenter states, that their educational and patient care missions would be compromised in the "long run"), should have been able to increase their FTE resident counts to their base year levels. If not by their most recent cost reporting period ending on or before September 30, 2002 then in time to qualify to make a timely request to use its cost report that includes July 1, 2003 under section 1886(h)(7)(A)(ii)(II) of the Act. We emphasize that the Congress recognized that, for a variety of reasons, a hospital's FTE resident count on its

most recent cost reporting period ending on or before September 30, 2002, might not be as high as it typically is, or that its FTE resident count may have increased after its most recent cost report ending on or before September 30, 2002. Under sections 1886(h)(7)(A)(ii)(II) and (III) of the Act, Congress provided for the possibility that hospitals may have expanded existing programs or may have planned to start new programs, by allowing hospitals the option to use their cost report that includes July 1, 2003 for expansions of existing programs, or to adjust the reference resident level in the case of newly approved programs. We believe hospitals that withdrew early (that is, those that withdrew so early from the demonstration that the time they were participating was shorter than the time they were not), and are committed to maintaining their residency programs consistent with its educational and patient care missions would have been able to substantially restore their residency programs by their cost report that includes July 1, 2003. Those hospitals that participated in the demonstration project for a lesser amount of time than they have been withdrawn and, since their withdrawal have been increasing their resident counts, could have availed themselves of the option to submit a timely request by June 14, 2004, to use their cost report that includes July 1, 2003, as the reference cost report.

In summary, we are finalizing our policy with respect to hospitals that participated in a demonstration project or the VRRP to state that if a hospital participated in the demonstration project or the VRRP for a longer period of time than the time period that it has been withdrawn from the demonstration project or the VRRP, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher

of the hospital's allopathic and osteopathic base number of residents, and the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, to the hospital's otherwise applicable FTE resident cap. If the higher of the allopathic and osteopathic base number of residents or the resident level in the hospital's most recent cost reporting period ending on or before September 30, 2002, is still less than the otherwise applicable FTE resident cap, we would reduce the hospital's FTE resident cap amount by 75 percent of the difference between the higher number and the otherwise applicable cap, effective July 1, 2005. We would also include those slots in the redistribution process under section 1886(h)(7)(B) of the Act since those slots are not "attributable" to participation in the demonstration project or the VRRP.

Under section 1886(h)(7)(A)(ii)(II) of the Act, a hospital may submit a timely request to use its cost report that includes July 1, 2003, for purposes of determining the reference resident level if the hospital has an expansion of an existing program that is not reflected on the hospital's most recent settled cost report. Accordingly, if a hospital that was participating in the demonstration project or the VRRP for a greater amount of time than it has been withdrawn from participation in the demonstration project or the VRRP, had an expansion of an existing program that is not reflected on its most recent settled cost report, and the hospital submitted (and CMS approved) a timely request that its resident level from its cost reporting period that includes July 1, 2003, be compared to its otherwise applicable FTE resident cap, we would compare the higher of the hospital's allopathic and osteopathic base number of residents, and the resident level in the

hospital's cost reporting period that includes July 1, 2003, to the hospital's otherwise applicable FTE resident cap. If the higher of the allopathic and osteopathic base number of residents or the resident level in the hospital's cost reporting period that includes July 1, 2003 is still less than the otherwise applicable FTE resident cap, we would reduce the hospital's FTE resident cap amount by 75 percent of the difference between the higher number and the otherwise applicable cap, effective July 1, 2005. We would also include those slots in the redistribution process under section 1886(h)(7)(B) of the Act since those slots are not "attributable" to participation in the demonstration project or the VRRP.

If a hospital participated in the demonstration project or the VRRP for an amount of time that is less than the amount of time that has elapsed since it withdrew from the demonstration project or the VRRP, such a hospital would be subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps. However, we note that such a hospital may still apply for an increase to its FTE caps as specified under section 1886(h)(7)(B) of the Act.

We are also clarifying one point concerning the "base number" of residents. In the May 18, 2004 proposed rule, we explained that for purposes of determining whether the FTE resident caps of hospitals that participated in the demonstration project or the VRRP would be reduced, we would determine the "difference between the number of unweighted allopathic and osteopathic residents training at the hospital at the start of a hospital's participation in the demonstration project or the VRRP, (that is, the base number of residents as defined by the terms of the demonstration project and the VRRP),

and the number of these residents training at the hospital in the hospital's most recent cost reporting period ending on or before September 30, 2002" (69 FR 28307, emphasis added). However, we inadvertently overlooked the fact that the demonstration project and the VRRP applied to dental and podiatric residents, in addition to allopathic and osteopathic residents. Thus, for hospitals that were training dental and podiatric residents at the start of their participation in the demonstration project or the VRRP, these residents were also included in the base number of residents. Because FTE resident caps apply only to allopathic and osteopathic residents, we are clarifying that, for purposes of determining possible reductions to the FTE resident caps of a hospital that participated in the demonstration project or the VRRP, any dental and podiatry FTE residents should be subtracted from a hospital's base number of FTE residents. If a hospital participated in the demonstration project or the VRRP for a longer period time than it was not participating, for purposes of determining possible reductions to the FTE resident caps, we would compare the higher of the hospital's base number of residents, excluding any dental and podiatric residents, and the reference resident level, to the hospital's otherwise applicable FTE resident cap.

l. Application of Section 422 to Hospitals That File Low Utilization Medicare Cost Reports

In general, section 422 of Pub. L. 108-173 applies to hospitals that are Medicare-participating providers and that train residents in approved residency programs. However, because Medicare-participating children's hospitals primarily serve a non-Medicare population and, therefore, receive minimal Medicare payments relative to

other Medicare-participating hospitals, some children's hospitals choose (with approval from their fiscal intermediaries) to submit low utilization (abbreviated) Medicare cost reports. Typically, such low utilization cost reports do not include the information that would be necessary for us to calculate Medicare GME payments, such as FTE resident counts and caps. Thus, children's hospitals that submit these low utilization cost reports do not receive Medicare GME payments.

Under section 1886(h)(7)(A) of the Act, as added by section 422(a) of Pub. L. 108-173, in the May 18, 2004 proposed rule (69 FR 28307), we proposed that determinations as to whether, and by how much, a children's hospital's FTE resident cap will be reduced will be made using the same methodology (that is, utilizing the same reference cost reporting periods and the same reference resident levels) that we proposed for other Medicare-participating teaching hospitals. We note that the low utilization cost reports may be filed with or without Worksheet E-3, Part IV (the worksheet on which the Medicare direct GME payment is calculated). If a children's hospital files a low utilization cost report in a given cost reporting period, and does not file the Worksheet E-3, Part IV, for Medicare purposes, that hospital is not considered by Medicare to be a teaching hospital in that cost reporting period. (We realize that a children's hospital that files a low utilization cost report may have a "resident cap" that is applicable for payment purposes under the Children's Hospital Graduate Medical Education (CHGME) Payment Program, administered by the Health Resources and Services Administration (HRSA), but this resident cap is not the Medicare FTE resident cap.) As stated in the One-Time Notification published on April 30, 2004 (Transmittal 77, CR 3247), if a children's

hospital filed a low utilization cost report in its most recent cost reporting period ending on or before September 30, 2002, and did not file the Worksheet E-3, Part IV, there could be no reduction under section 1886(h)(7)(A) of the Act because there is no reference resident level for such a hospital. This would be the case even in instances where such a children's hospital has a FTE resident cap (for example, from 1996) that is recognized for Medicare purposes, because there would still be no reference resident level for its most recent cost reporting period ending on or before September 30, 2002, on which to determine a possible reduction to the children's hospital FTE resident cap.

Although section 1886(h)(7)(A) of the Act does not apply to children's hospitals that filed a low utilization cost report (and no Worksheet E-3, Part IV) for the most recent cost reporting period ending on or before September 30, 2002, we proposed that, regardless of how a children's hospital has previously filed its Medicare cost report (that is, a full cost report or an abbreviated one), or how it is treated for CHGME payment purposes, a children's hospital would be eligible to apply for an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, subject to the same demonstrated likelihood and evaluation criteria proposed above for all hospitals. However, we proposed that, in order to receive an increase in its FTE resident cap under section 1886(h)(7)(B) of the Act, effective July 1, 2005, in addition to complying with the proposed application requirements described above, the hospital must file Worksheet E-3, Part IV, with its Medicare cost report for its cost reporting period that includes July 1, 2005. We proposed that the children's hospital comply with this requirement because section 422 is intended to allow a hospital to increase its FTE counts for

purposes of Medicare GME payments. We do not believe it would be appropriate to grant an increase in a hospital's FTE resident cap under section 1886(h)(7)(B) of the Act if the hospital does not use the slots for Medicare purposes (but only for purposes of the CHGME Payment Program) as would be evidenced by not filing a Worksheet E-3, Part IV.

Comment: Several commenters requested that we exempt all children's hospitals or hospitals filing a low utilization Medicare cost report, or both, from possible reductions to FTE resident caps under section 422 of Pub. L. 108-173. The commenters pointed out that Medicare-participating children's hospitals primarily serve a non-Medicare population and may choose (with approval from their fiscal intermediary) to submit low utilization (abbreviated) cost reports. They added that, although not a required part of a low utilization Medicare cost report, some children's hospitals may have filed Worksheet E-3, Part IV with the cost report. The commenters indicated that Worksheet E-3, Part IV details the hospital's FTE resident count and FTE resident cap for direct GME purposes and that CMS proposed to apply the provisions of section 1886(h)(7)(A) of the Act if the low utilization filer had filed Worksheet E-3, Part IV for the reference cost reporting period. The commenters believed it would be unfair to distinguish between low utilization filers based on the inclusion of Worksheet E-3, Part IV and, therefore, possibly make reductions to the FTE resident cap for some low utilization filers and not for others. They requested that we deem submission of Worksheet E-3, Part IV to be irrelevant to whether FTE reductions apply to any low utilization filers. Another commenter requested that we not apply FTE resident cap

reductions to children's hospitals that submitted low utilization reports in the 1996 base year.

Response: We believe the commenters have taken the policy regarding low utilization filers out of context. Low utilization cost reports may be filed with or without Worksheet E-3, Part IV. The proposed rule does not exempt any of these low utilization filers from the provisions of section 422. Rather, as we stated in the May 18, 2004 proposed rule (69 FR 28308), "if a children's hospital filed a low utilization cost report in its most recent cost reporting period ending on or before September 30, 2002, and did not file the Worksheet E-3, Part IV, there could be no reduction under section 1886(h)(7)(A) of the Act because there is no reference resident level for such a hospital." (Emphasis added.) Our policy focuses on the existence of a reference resident level rather than if the hospital is filing a low utilization cost report. Therefore, as we stated in the proposed rule, section 1886(h)(7)(A) of the Act does not apply to children's hospitals that filed a low utilization cost report and did not file Worksheet E-3, Part IV because, for these hospitals, no reference FTE resident count exists. Furthermore, we do not have the authority to exempt hospitals from possible reductions under section 422. The only hospitals that are exempted by statute are rural hospitals with fewer than 250 beds, as explicitly mandated by section 1886(h)(7)(A)(i)(II) of the Act. Therefore, we do not have the authority to exempt children's hospitals that file a low utilization cost report either in the reference year or in the 1996 base year.

Comment: One commenter noted that children's hospitals that file low utilization cost reports may not have filed Worksheet E-3, Part IV and, therefore, may not have the

prior and penultimate years' FTE resident counts necessary to calculate the rolling average FTE resident count after receiving an increase in FTE resident caps in accordance with section 422 of Pub. L. 108-173. The commenter proposed that if a children's hospital has not filed Worksheet E-3, Part IV with its low utilization cost reports, the hospital include supporting documentation, such as the prior periods' Form HRSA-99 forms with the request for an increase in its FTE resident cap, for the purposes of computing the rolling average.

Response: We agree with the commenter that a children's hospital that files low utilization cost reports without Worksheet E-3, Part IV must supply whatever supporting documentation as may be deemed necessary to the financial intermediary in order to calculate a 3-year rolling average FTE resident count. However, we note, that as explained earlier in this final rule, we excluded any FTE resident cap increases that a hospital may receive as a result of section 422 (the section 422 cap) from the rolling average determination. Therefore, the process of collecting documentation necessary for calculating a rolling average would only apply to calculation of the number of residents at the hospital that are subject to a hospital's 1996 FTE resident cap, not to FTE residents counted for purposes of the section 422 cap.

Comment: One commenter requested that CMS emphasize that the redistribution of FTE resident cap slots under section 1886(h)(7)(A) of the Act applies only to the Medicare program. The commenter pointed out that many children's hospitals qualify for annual grants under the federal Children's Hospitals GME (CHGME) Payment Program, which is administered by the Health Resources and Services Administration

(HRSA). The commenter added that, by statute, HRSA determines the FTE resident counts for CHGME payment purposes based on Medicare rules regarding counting FTE residents (42 U.S.C §256e(c)(1)(B)). The commenter believed it would be inappropriate for HRSA to enact any provisions of Pub. L. 108-173 that would result in reductions (or increases) to children's hospital's FTE resident cap and requested that CMS clearly explain that section 1886(h)(7) of the Act applies only to the Medicare program.

Response: While we appreciate the commenter's concerns regarding the effects of section 422 of Pub. L. 108-173 on the CHGME Payment Program, we have no authority to limit HRSA's use of CMS' determinations. All comments on CHGME should be directed to HRSA.

m. CMS Evaluation Form

CMS Evaluation Form
As Part of the Application for the Increase in a Hospital's FTE Cap(s) under Section 422 of the Medicare Modernization Act of 2003

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). The applicant hospital is responsible for complying with the other requirements listed in the FY 2005 hospital inpatient prospective payment system rule in order to complete its application for the increase in its FTE cap(s) under section 422 of Public Law 108-173.

NAME OF HOSPITAL: _____

MEDICARE PROVIDER NUMBER: _____

NAME OF SPECIALTY TRAINING PROGRAM: **_____**

(Check one): □ Allopathic Program □ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR PROGRAM:

Direct GME: _____ IME: _____

Section A: Demonstrated Likelihood of Filling the FTE Slots

(Place an "X" in the box for the applicable criterion and subcriteria.)

□ A1: Demonstrated Likelihood Criterion 1. The hospital intends to use the additional FTEs to establish a new residency program (listed above) on or after July 1, 2005 (that is, a newly approved program that begins training residents at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2005).

☐ (1) Hospital will establish this newly approved residency program. **(Check at least one of the following, if applicable.)**

☐ Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS by December 1, 2004. **(Copy attached.)**

☐ The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program by December 1, 2004. **(Copy attached.)**

☐ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(Copy attached.)**

☐ (2) Hospital will likely fill the slots requested. **(Check at least one of the following, if applicable.)**

☐ The hospital's existing residency programs had a resident fill rate of at least 85 percent in each of program years 2001 through 2003. **(Documentation attached.)**

☐ The specialty program (listed above) has a resident fill rate either nationally, within the State, or within the MSA in which the hospital is located, of at least 85 percent. **(Documentation attached.)**

☐ A2: Demonstrated Likelihood Criterion 2. The applying hospital intends to use the additional FTEs to expand the existing residency training program that is listed above (that is, to increase the number of FTE resident slots in the program) on or after July 1, 2005, and before July 1, 2008.

☐ (1) Hospital intends to expand an existing program. **(Check at least one of the following, if applicable.)**

☐ The appropriate accrediting body (the ACGME, AOA or ABMS) has approved the hospital's expansion of the number of FTE residents in the program. **(Documentation attached.)**

☐ The American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. **(Documentation attached.)**

☐ The hospital has submitted an institutional review document or program information form for the expansion of the existing residency training program by December 1, 2004. **(Copy attached.)**

☐ (2) Hospital will likely fill the slots of the expanded residency program. (**Check at least one of the following, if applicable.)**

☐ Hospital has other previously established residency programs, with a resident fill rate of at least 85 percent in each of program years 2001 through 2003.) **(Documentation attached.)**

☐ Hospital is expanding an existing program in a particular specialty with a resident fill rate either nationally, within the State, or within the MSA in which the hospital is located, of at least 85 percent. **(Documentation attached.)**

☐ Hospital is expanding a program in order to train residents that need a program because another hospital in the State has closed a similar program, and the applying hospital received a temporary adjustment to its FTE cap(s) (under the requirements of §413.79(h)). **(Documentation attached.)**

☐ A3: Demonstrated Likelihood Criterion 3. Hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both. **(Copies of EACH of the following attached.)**

● Copies of the most recent as-submitted Medicare cost reports documenting on Worksheet E, Part A and Worksheet E3, Part IV the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

● Copies of the 2004 residency match information concerning the number of residents at the hospital in its existing programs.

● Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

☐ B1: First Level Priority Category: The hospital is a rural hospital as of October 1, 2004 and has the only specialty training program in the State (for the program requested on this CMS Evaluation Form).

☐ B2: Second Level Priority Category: The hospital is a rural hospital as of October 1, 2004 only.

☐ B3: Third Level Priority Category: The hospital is in an other than large urban area, as of October 1, 2004, and the request is for only specialty program in the State (for the program requested on this CMS Evaluation Form).

☐ B4: Fourth Level Priority Category: The hospital is in an other than large urban area, hospital, as of October 1, 2004.

☐ B5: Fifth Level Priority Category: The hospital request is for the only specialty training program in the State (for the program requested on this CMS Evaluation Form).

☐ B6: Sixth Level Priority Category: The hospital meets none of the statutory priority criteria.

Section C. Evaluation Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

☐ C1: Evaluation Criterion One. The hospital that is requesting the increase in its FTE resident cap(s) has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report.

☐ C2: Evaluation Criterion Two. The hospital needs the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program.

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☐ C3: Evaluation Criterion Three. The hospital does not qualify for an adjustment to its FTE caps under existing §413.86(g)(12) for a rural track residency program, but is applying for an increase in its FTE resident cap(s) under section 1886(h)(7)(B) of the Act because it rotates (or in the case of a new program, will rotate) residents for at least 25 percent of the duration of the residency program to any one (or in combination thereof) of the following: a rural area, as defined in section 1886(d)(2)(D)(ii) of the Act and §412.62(f)(1)(iii) of the regulations; a rural health clinic (RHC), as defined in section 1861(aa)(1) of the Act and §491.2 of the regulations; or a Federally Qualified Health Center (FQHC), as defined in section 1861(a)(3) of the Act and §405.2401(b) of the regulations.

☐ C4: Evaluation Criterion Four. In portions of cost reporting periods prior to July 1, 2005, the hospital qualified for a temporary adjustment to its FTE cap under existing §413.86(g)(9) because it was training displaced residents from either a closed program or a closed hospital, and, even after the temporary adjustment, the hospital continues to train residents in the specialty(ies) of the displaced residents and is above the hospital's direct GME FTE cap or IME FTE cap, or both, for that reason.

☐ C5: Evaluation Criterion Five. The hospital is above its FTE caps because it was awaiting accreditation of a new program from the ACGME or the AOA during the base period for its FTE cap(s) but was not eligible to receive a new program adjustment as stated under existing §413.86(g)(6)(ii).

☐ C6: Evaluation Criterion Six. The hospital is above its FTE resident caps because, despite qualifying for an FTE cap adjustment for a new program under §413.86(g)(6)(i) or (g)(6)(ii), it was unable to "grow" its program to the full complement of residents for which the program was accredited before the hospital's FTE resident cap was permanently set beginning with the fourth program year of the new program.

☐ C7: Evaluation Criterion Seven. The hospital is located in any one (or in combination thereof) of the following: a geographic HPSA, as defined in 42 CFR 5.2; a population HPSA, (also defined at 42 CFR 5.2); or a Medicare physician scarcity county, as defined under section 413 of Public Law 108-173.

□ C8: Evaluation Criterion Eight. The hospital is in a rural area (as defined under section 1886(d)(2)(D)(ii) of the Act) and is a training site for a rural track residency program (as specified under §413.86(g)(12), but is unable to count all of the FTE residents training at the rural hospital in the rural track because the rural hospital's FTE cap is lower than the hospital's unweighted count of allopathic or osteopathic FTE residents beginning with portions of cost reporting periods on or after July 1, 2005.

□ C9: Evaluation Criterion Nine. The hospital is affiliated with a historically Black medical college.

□ C10: Evaluation Criterion Ten: The hospital is training residents in residency program(s) sponsored by a medical school(s) that is designated as a Center of Excellence for Underserved Minorities (COE) under section 736 of the Public Health Service Act in FY 2003.

□ C11: Evaluation Criterion Eleven: The hospital needs the additional slots to establish a new primary care residency program, or to expand an existing primary care residency program, as primary care is defined under 413.75(b).

□ C12: Evaluation Criterion Twelve: The hospital is above its direct GME and/or IME FTE cap on the count of residents, as stated in the Medicare cost report on the worksheets E, part A or the worksheets E3, part IV, in the hospital's most recently as submitted Medicare Cost Report.

□ C13: Evaluation Criterion Thirteen: The hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) of the Act because the resident level in its reference cost report equaled or was above its FTE resident cap as it knew its FTE resident cap to be at that time, but as a result of a resolution to an appeal concerning the FTE resident cap, the FTE resident cap was later increased to an amount that is greater than the reference resident level.

□ C14: Evaluation Criterion Fourteen: The hospital is above its cap and needs the additional slots to establish a new emergency medicine residency program or expand an existing emergency medicine residency program. The emergency medicine residency program includes training in bio-terrorism preparedness.

□ C15: Evaluation Criterion Fifteen: The hospital's FTE resident cap was reduced under section 1886(h)(7)(A)(i) and:

☐ The hospital started a new program(s) that was accredited before January 1, 2002;

☐ The new program was in operation during the reference cost reporting period; and

☐ The program has been in operation (training residents) for three or fewer years by July 1, 2003.

n. Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number of the hospital.
- The total number of requested FTE resident slots for direct GME or IME, or both, up to 25 direct GME FTE and 25 IME FTE per hospital.
- A completed copy of the CMS Evaluation Form for each residency program for which the hospital intends to use the requested increase in FTE residents. This form can be found at: http://www.cms.hhs.gov/forms/.
- Source documentation to support the assertions made by the hospital on the CMS Evaluation Form. For example: if the hospital indicates on the Evaluation Form that it is located in a geographic Health Professions Shortage Area (HPSA), the hospital would include documentation to support that assertion.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report.
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

The completed application and supporting documentation (as described above) must be submitted to the CMS Central Office and the CMS Regional Office for the region in which the applicant hospital is located. The application must be received on or before December 1, 2004. The addresses of the CMS central office and regional offices are listed below.

We note that some hospitals' FTE counts will be subject to audit for the purposes of section 1886(h)(7)(A) of the Act and those audits may not be completed by December 1, 2004. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap, we will allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for the purposes of section 1886(h)(7)(A) of the Act, and that

hospital also wishes to apply for an increase in its FTE resident cap(s), that hospital must submit a completed application to CMS that is received on or before March 1, 2005.

CMS Central and CMS Regional Office Mailing Addresses for Applications for Increases in FTE Resident Caps:

Central Office

Centers for Medicare and Medicaid Services (CMS)
Director, Division of Acute Care
7500 Security Boulevard
Mail Stop C4-08-06
Baltimore, Maryland 21244

Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region I
JFK Federal Building
Room 2325
Boston, MA 02203
Phone: (617) 565-1185

Region II (New York, New Jersey, U.S. Virgin Islands, and Puerto Rico):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region II
26 Federal Plaza, 38th Floor
New York, NY 10278
Phone: (212) 264-3657

Region III (Delaware, Maryland, Pennsylvania, Virginia and West Virginia, and the District of Columbia):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region III
Public Ledger Building, Suite 216
150 South Independence Mall West
Philadelphia, PA 19106
Phone: (215) 861-4140

Region IV (Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, and Tennessee):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region IV
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909
Phone: (404) 562-7500

Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region V
233 North Michigan Avenue, Suite 600
Chicago, IL 60601
Phone: (312) 886-6432

Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region VI
1301 Young Street, Suite 714
Dallas, TX 75202
Phone: (214) 767-6423

Region VII (Iowa, Kansas, Missouri, and Nebraska):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region VII
Richard Bolling Federal Building
Room 235
601 East 12th Street
Kansas City, MO 64106

Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region VIII
Colorado State Bank Building
1600 Broadway, Suite 700
Denver, CO 80202
Phone: (303) 844-2111

Region IX (Arizona, California, Hawaii, and Nevada and Territories of American Samoa, Guam and the Commonwealth of the Northern Mariana Islands):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region IX
75 Hawthorne St., Suite 408
San Francisco, CA 94105
Phone: (415) 744-3501

Region X (Alaska, Idaho, Oregon, and Washington):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region X
2201 Sixth Avenue, MS-40
Seattle, WA 98121
Phone: (206) 615-2306

3. Direct GME Initial Residency Period (new §413.79, a redesignation of existing §413.86(g))

a. Background

As we have generally described above, the amount of direct GME payment to a hospital is based in part on the number of FTE residents who are training at the hospital during a year. The number of FTE residents training at a hospital, and thus the amount of

direct GME payment to a hospital, is directly affected by CMS policy on how "initial residency periods" are determined for residents.

Section 1886(h)(5)(A) of the Act defines "approved medical residency training program" as "a residency or other postgraduate medical training program, participation in which may be counted toward certification in a specialty or subspecialty." This provision is implemented in regulations at existing §413.86(b). In accordance with section 1886(h)(5)(I) of the Act, the term "resident" is defined to include "an intern or other participant in an approved medical residency training program." Existing §413.86(b) defines "resident" as an "intern, resident, or fellow who participates in an approved medical residency training program . . . as required in order to become certified by the appropriate specialty board."

Section 1886(h)(4)(C)(ii) of the Act provides that while a resident is in the "initial residency period," the resident is weighted at 1.00 (existing §413.86(g)(2) of the regulations). Section 1886(h)(4)(C)(iii) of the Act requires that if a resident is "not in the resident's initial residency period," the resident is weighted as .50 FTE resident (existing §413.86(g)(3) of the regulations).

Section 1886(h)(5)(F) of the Act defines "initial residency period" as the "period of board eligibility," and, subject to specific exceptions, limits the initial residency period to an "aggregate period of formal training" of no more than 5 years for any individual. Section 1886(h)(5)(G) of the Act generally defines "period of board eligibility" for a resident as "the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident

is training." Existing §413.86(g)(1) of the regulations generally defines "initial residency period" as the "minimum number of years required for board eligibility." Existing §413.86(g)(1)(iv) provides that "time spent in residency programs that do not lead to certification in a specialty or subspecialty, but that otherwise meet the definition of approved programs . . . is counted toward the initial residency period limitation." Section 1886(h)(5)(F) of the Act further provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program."

The initial residency period is determined as of the time the resident enters the "initial" or first residency training program and is based on the period of board eligibility associated with that medical specialty. Thus, this provision limits the amount of direct GME that Medicare pays a hospital for a resident who switches specialties to a program with a longer period of board eligibility or completes training in a specialty and then continues training in a subspecialty (for example, cardiology and gastroenterology are subspecialties of internal medicine).

b. Direct GME Initial Residency Period Limitation: Simultaneous Match Issue

We understand there are numerous programs, including anesthesiology, dermatology, psychiatry, and radiology, that require a year of generalized clinical training to be used as a prerequisite for the subsequent training in the particular specialty. For example, in order to become board eligible in anesthesiology, a resident must first complete a generalized training year and then complete 3 years of training in anesthesiology. This first year of generalized residency training is commonly known as

the "clinical base year." Commonly, the clinical base year requirement is fulfilled by completing either a preliminary year in internal medicine (although the preliminary year can also be in other specialties such as general surgery or family practice), or a transitional year program (which is not associated with any particular medical specialty).

In many cases, during the final year of medical school, medical students apply for training in specialty programs. Typically, a medical student who wants to train to become a specialist is "matched" to both the clinical base year program and the residency training specialty program at the same time. For example, the medical student who wants to become an anesthesiologist will apply and "match" simultaneously for a clinical base year in an internal medicine program for year 1 and for an anesthesiology training program in years 2, 3, and 4.

Based on our interpretation of the statute, our policy is that the initial residency period is determined for a resident based on the program in which he or she participates in the resident's first year of training, without regard to the specialty in which the resident ultimately seeks board certification. Therefore, for example, a resident that chooses to fulfill the clinical base year requirement for an anesthesiology program with a preliminary year in an internal medicine program will be "labeled" with the initial residency period associated with internal medicine, or 3 years (3 years of training are required to become board eligible in internal medicine), even though the resident may seek board certification in anesthesiology, which requires a minimum of 4 years of training to become board eligible. As a result, this resident would be weighted at 0.5 FTE in his or her fourth year of training for purposes of direct GME payment.

We understand that some hospitals have been assigning residents that complete a clinical base year in a different specialty from the one in which they ultimately train an initial residency period and a weighting factor based on the specialty associated with second program year in which the residents train. As a result, some residents have been assigned a weighting factor of 1.0 FTE for years beyond their initial residency periods, rather than the applicable 0.5 FTE weighting factor. This error results in Medicare overpayments, the size of which is dependent upon the hospital's direct GME PRA and its Medicare utilization. In addition, we have received numerous requests from the health care industry to revise our policy concerning the initial residency period for residency programs that require a clinical base year because some entities in the industry believe that our current policy is unfair to those individuals who "match" simultaneously for both a preliminary year (for example, the clinical base year in internal medicine) and the longer specialty residency program (for example, anesthesiology, dermatology, or radiology).

To address these concerns, in the May 18, 2004 proposed rule (69 FR 28311), we indicated that we were considering making a change in policy that addresses these "simultaneous match" residents. Specifically, we were considering a policy that, if a hospital can document that a particular resident matches simultaneously for a first year of training in a clinical base year in one medical specialty, and for additional year(s) of training in a different specialty program, the resident's initial residency period would be based on the period of board eligibility associated with the specialty program in which the resident matches for the subsequent year(s) of training and not on the period of board

eligibility associated with the clinical base year program, for purposes of direct GME payment. In addition, we considered a new definition of "residency match" to mean, for purposes of direct GME, a national process by which applicants to approved medical residency programs are paired with programs on the basis of preferences expressed by both the applicants and the program directors.

This policy could apply regardless of whether the resident completes the first year of training in a separately accredited transitional year program or in a preliminary (or first) year in another residency training program such as internal medicine.

Under this policy, hospitals would apply a weight of 1.0 FTE (instead of 0.5) for an additional year or two to some residents who, as a prerequisite for training in a specialty program, complete a first year of training in a different specialty program. This would probably cause an increase in direct GME payments. This provision would apply to such programs as anesthesiology, dermatology, radiology, and physical medicine and rehabilitation. In 2004, there were approximately 1,840 residents in these specialties that would be affected by this proposal, as compared to the approximately 83,000 residents in total for whom Medicare makes direct GME payments. Under current policy, these 1,840 residents would be weighted at 0.5 FTE in their 4th year (and 5th year, if applicable) of training. Therefore, direct GME spending for these 1,840 residents should currently be $26.5 million (1,840 x 0.5 x 82,249[1] x .35[2]). We indicated in the proposed rule that, under the policy we are considering, direct GME spending would be twice that amount at $53 million (1,840 x $82,249 x .35). However, because we believe a number of fiscal

[1] $82,249 is the estimated national average per resident amount for FY 2005.
[2] .35 is the estimated average Medicare utilization.

intermediaries may have been applying current policy incorrectly and instead have been weighting approximately 920 residents at 1.0 in their 4th year (and 5th year, if applicable) of training, the cost of this change would be expected to be closer to $13.25 million (920 x 0.5 x $82,249 x .35). We provided this cost impact analysis to the public for its information in consideration of any such proposed change.

We note that in the Conference Committee report that accompanied Pub. L. 108-173, the Committee stated that "The conferees also clarify that under section 1886 (h)(5)(F) of the Act, the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training." (Conference Committee Agreement Accompanying Pub. L. 108-173, 108 Cong., 2d Sess., 276 (2003)) The Conference Committee included this language as part of its explanation of section 712 of Pub. L. 108-173, which clarifies an exception to the initial residency period for geriatric fellowship programs (see section IV.O.3.c. of this preamble). We indicated in the proposed rule that we were considering making a policy change for determining the initial residency period for a resident who participates in a clinical base year program based on the resident's second year of training, as the Conference Committee suggests. However, we understand that not all residents who participate in the clinical base year programs simultaneously match in specialty training programs before the residents' first year of training. Thus, if we were to propose a "second year" policy, there would be no way to distinguish in the second year of training among those residents who simultaneously matched in a specialty program prior to their first year of training; those

residents who did not match simultaneously, but participated in a clinical base year and then continued on to train in a different specialty; and those residents who simply switched specialties in their second year. As we have stated earlier, the initial residency period is to be determined based on the "initial" or first program in which a resident trains. Section 1886(h)(5)(F) of the Act provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program." (Emphasis added.)

Therefore, we indicated in the proposed rule that we believe it is appropriate for us to consider changes to the "simultaneous match" policy that would allow for documentation that the residents' training program is arranged to continue in another medical specialty after the resident completes the clinical base year. However, we also specifically solicited comments concerning the issue of how to establish the initial residency period for a resident who does not match simultaneously for the first and second year, completes the first year in a preliminary program in one specialty, and then continues his or her training in a different specialty program that requires completion of a clinical base year.

In the proposed rule, we note that if we were to propose this change in the initial residency period policy, the change, if finalized, could result in an adjustment to the PRA applicable for the direct GME payments made to the hospital for a resident in a clinical base year. By treating the first year as part of a nonprimary care specialty program (for example, anesthesiology), the hospital would be paid at the lower nonprimary care PRA rather than the higher primary care PRA, which would be used for residents training in a

clinical base year in a primary care program (for example, internal medicine). We noted in conjunction with our proposal that the initial residency period would be established based upon the period of board eligibility for the specialty program for residents who simultaneously match with a clinical base year and a specialty program that we believe all of the programs that require a clinical base year are nonprimary care specialties. Because we were considering a policy change that the initial residency period would be based upon the period of board eligibility for the specialty program rather than the clinical base year, we indicated that we would also consider a policy change that the nonprimary care PRA would apply for the duration of their initial residency period.

Thus, as we indicated in the proposed rule, we are considering making the above policy changes to address the clinical base year initial residency period issue. We specifically solicited comments on the changes we were considering to the existing initial residency period policy and other approaches to address this issue, particularly those that do not increase Medicare expenditures.

Comment: We received many comments commending CMS for the proposed policy discussion concerning residency training in specialties that require a clinical base year. One commenter stated that "we agree that, for purposes of direct GME payment, a resident's initial residency period should be based on the period of board eligibility associated with the specialty program in which the resident matches for the subsequent year(s) of training and not on the period of board of board eligibility associated with the clinical base year program."

However, many commenters believed that instead of a "simultaneous match" policy, CMS should adopt as final the policy stated in the Conference Committee report that accompanied Pub. L. 108-173, in which the conferees clarified that the initial residency period for any residency "for which ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training." (Conference Committee Agreement Accompanying Pub. L. 108-173, 108 Cong., 2d Sess., 276 (2003)). Many commenters further stated that "CMS should make a clear statement that for a resident whose first year of training is completed in a program that provides a general clinical base year as required by the ACGME for certain specialties, an IRP should be assigned in the second year based on the specialty the resident enters in the second year of training." The commenters believed that not having a "second year" policy for determining the IRP for those residents that must complete a clinical base year "violates the statute, does not reflect congressional intent, and results in inequitable payments to teaching hospitals for residents training in certain specialties."

Response: We appreciate the comments that compliment our proposal to clarify the direct GME policy on determining the IRP for residents that complete a clinical base year of training and simultaneous match in the clinical base year program and the specialty training program. We understand the provider community's enthusiasm for a "second year" policy for determining the IRP for residents who must complete a clinical base year. However, as we have stated above and also in the proposed rule, we believe that if we were to propose a "second year" policy, there would be no way to distinguish among those residents in their second year of training who simultaneously match in a

specialty program prior to their first year of training; those residents who participated in a clinical base year and then continued on in a specialty; and those residents who simply switched specialties in their second year. We believe that the proposed simultaneous match policy is more consistent with congressional intent, as stated in the statute. As we discussed above, and also in the proposed rule, we believe the statute requires that the initial residency period be determined based on the "initial" or first program in which a resident trains. Section 1886 (h)(5)(F) of the Act provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program." (Emphasis added.) Thus, we believe that our proposed "simultaneous match" policy will allow for auditable documentation of the residents' intent upon entering the clinical base year and is therefore appropriate.

We stated in the proposed rule that we believe "it is appropriate for us to consider changes to the 'simultaneous match' policy that would allow for documentation that the residents' training program is arranged to continue in another medical specialty after the resident completes the clinical base year" (69 FR 28312). We have not heard from the public on how a "second year" policy could be documented at the time the resident enters the residency program (that is, the clinical base year), so that we may distinguish between residents who fully intend to complete a different medical specialty at the start of the clinical base year and other residents who complete a clinical base year. We recognize that there may be some disparity in counting residents for direct GME who simultaneously match in a clinical base year and a different specialty, and those residents who complete a clinical base year and then go on to a different specialty program.

However, we believe the policy we proposed will be effective in correcting the problem of many of the residents who are "caught" by our IRP policies. Therefore, we believe it is appropriate to finalize the simultaneous match policy to state at §413.79(a): "effective October 1, 2004, if a hospital can document that a particular resident matches simultaneously for a first year of training in a clinical base year, and for a second year of training in the specialty program in which the resident intends to seek board certification, the resident's initial residency period would be based on the specific specialty program for the subsequent year(s) of training in which the resident matches and not on the clinical base year program."

Comment: Similar to the comments above, one commenter stated that it did not believe the statute requires CMS to determine the IRP for residents who must complete a clinical base year of training in the first year of the resident's first year of training, and advocated a second year IRP policy for such residents. The commenter noted that CMS's policy allowing the initial residency period to be determined in the second year for residents training in transitional year programs "is clear evidence that such a timeframe is permissible under the statute."

Response: As stated above, we believe that our proposed simultaneous match policy is the more appropriate policy to finalize than a second year policy for residents training in a clinical base year. The statute requires that the initial residency period be determined based on the "initial" or first program in which a resident trains. Section 1886 (h)(5)(F) of the Act provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training

program." (Emphasis added.) The simultaneous match policy will allow for hospitals to document the residents' intent upon entering the clinical base year, as the statute requires.

As we mentioned above and also in the proposed rule, the clinical base year requirement can be fulfilled by residents that train in preliminary medicine, which is the first year of an internal medicine residency, or transitional years programs, which are unaffiliated with a particular specialty. For a resident that matches in a transitional year program and simultaneously matches in a specialty training program, Medicare will use the specialty training program to determines that resident's IRP. In the limited circumstance where a resident trains in the transitional year program, without simultaneously matching in a specialty program, Medicare is simply unable to determine what specialty the resident has "entered" for purposes of determining that resident's IRP. The earliest moment that Medicare is able to determine such a resident's IRP is when the resident "enters" the specialty program—the resident's second year of training. Thus, in the limited circumstance of a resident that trains in a transitional year program that is unaffiliated with a particular specialty and does not simultaneously match in a specialty program, Medicare will look to the resident's second year of training as when the resident has "entered" the residency program for purposes of determining the IRP. We note that this situation of the transitional year program is substantially different from the situation where the resident begins training in a specialty, for example, internal medicine, as the resident's clinical base year. In the latter case, we are able to establish an initial residency period based on the number of years required for certification in that specialty and have no need to wait until the second year.

Comment: One commenter believed that our proposed definition of "residency match," a national process by which applicants to approved medical residency programs are paired with programs on the basis of preferences expressed by both the applicants and the program directors, is unclear and ambiguous in regard to residents who are in a required clinical base year training program. The commenter requested clarification from CMS.

Response: We are finalizing a policy with this final rule that states that, effective October 1, 2004, if a hospital can document that a particular resident has matched simultaneously for a first year of training in a clinical base year, and for a second year of training in the specialty program in which the resident intends to seek board certification, the resident's initial residency period (IRP) will be based on the specific specialty program in which the resident matched for the subsequent year(s) of training, and not based on the clinical base year program, for purposes of direct GME payment. We understand that the term, "residency match" is commonly used by both providers and residents. We are defining "residency match" to mean, for purposes of Medicare direct GME, a national process carried out by the National Residency Matching Program (NRMP), the San Francisco Matching Program, the Urology Matching Program, or the American Osteopathic Association Residency Match Program by which applicants to approved medical residency programs are formally paired with programs on the basis of preferences expressed by both the applicants and the program directors.

Comment: Several commenters noted that they "had no knowledge of any prior CMS policy that is in any way conflicted with the provisions of the legislative history."

These commenters state it was "always" their understanding that the IRP was set in the second year for residents that have undertaken a clinical base year during their first year of residency. The commenters also state that the fiscal intermediaries servicing the hospitals have "never expressed disagreement with this policy."

Similarly, another commenter specifically requested that CMS not implement the proposed clarification to apply the possibly shorter initial residency period for the specialty associated with the clinical base year prior to portions of cost reporting periods on or before October 1, 2004.

Finally, another commenter stated that CMS "has never previously issued any formal rule regarding how clinical base year training affects the determination of the initial residency period."

Response: We believe that we have consistently held to our policy concerning the determination of the IRP for residents that complete a clinical base year. We have stated that section 1886(h)(5)(F) of the Act provides that "the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program." (Emphasis added.) Thus, until the effective date of this final rule, our policy has been that, for a resident that completes a clinical base year, the initial residency period for this resident is determined based on the period of board eligibility for the specialty associated with the first (that is, clinical base year) program. We are prospectively changing this policy in this final rule for those residents that simultaneously match, as explained further in this preamble, effective October 1, 2004.

To address the commenters point concerning the actions of the fiscal intermediaries on this policy, we are not in a position to specifically respond at this time regarding how some intermediaries may have determined initial residency periods for particular residents. However, we understand that there are many teaching hospitals around the country that have been determining IRPs for residents that complete clinical base years correctly (that is, based on our longstanding policy that has been in effect until this final notice). In this rule, we are responding to comments regarding our proposed policy and prospectively revising our current policy. There are other avenues, outside of this final rule, through which the commenter's concerns regarding our current policy could be appropriately addressed.

Comment: We received several comments on our proposal to apply the non-primary care PRA for the duration of the initial residency period for residents that simultaneously matched in a clinical base year program and a longer specialty program. The commenters believed that there is "nothing in the MMA's legislative history that would indicate that such an adjustment is necessary. Accordingly, it is unclear why any change to this policy would now be required."

Response: We proposed a policy change to determine the initial residency period for residents that simultaneously match for both a clinical base year and a subsequent specialty program based upon the period of board eligibility for the subsequent specialty program, that is, the program in which the resident will seek certification. We believed, and continue to believe, it is appropriate to propose a policy that treats residents consistently in terms of the specialty program in which they are considered to be training.

When the specialty program for which the resident simultaneously matches for the second year is a non-primary care specialty, under our policy as revised under this final rule, we would assign the IRP in the resident's first year of training based on the period of board eligibility associated with the non-primary care specialty. Thus, we believe it is consistent to apply the non-primary care PRA for that resident's FTE time, even during the first, clinical base year of training and we are finalizing this policy at §413.77(f) of the regulations.

Comment: We received one comment which stated that there are teaching hospitals that have "historically called the first year of training for these complex specialties a "general clinical year," instead of a "transitional year…" For this reason, the commenter states the hospitals are "significantly, adversely affected by not being allowed to count the full value of FTEs training in these specialties, when, in fact, there is no difference between a "general clinical year" and a "transitional year." This "penalty for semantics" is illogical, and obviously, unfair."

Another commenter described the general practice residency (GPR) for dentistry. The commenter states that the GPR program should be treated as a transitional year program (like an allopathic program), with the initial residency period for a resident who completes a GPR program determined by the IRP for the program the resident enters next, that is, the specialty program.

Response: In contrast to other comments received, we believe the above commenters are describing a situation where hospitals were aware of our current policy on determining the initial residency period for residents that complete a clinical base

year. As we stated above, and also in the proposed rule, we believe there are stand-alone transitional year programs that are separately accredited one-year programs unaffiliated with a particular specialty. There are also other clinical base year programs, which are affiliated with a particular medical specialty and when a resident completes a year of training in that program, that year could be counted toward board certification in that specialty. We do not know the nature of the programs the commenters have labeled as a "general clinical year," and, "general practice residency," therefore, cannot respond to the commenters' specific circumstances. We note that the distinction between a transitional year program, which is not associated with any particular medical specialty, and other clinical base year programs that are associated with a particular specialty and participation in which can be counted toward board certification in that specialty, remains applicable regardless of "semantics" or the "terminology" a hospital uses for its clinical base year programs. Thus, "semantics" or terminology is not the basis on which a fiscal intermediary should determine the initial residency period of a particular resident.

Comment: One commenter argued strongly for the adoption of a "second year policy" (that is, a policy under which the IRP for all residents would be established based upon the period of board eligibility for the specialty in which the resident trains in the second residency year). The commenter stated that, "CMS proposal suffers from the practical difficulty that determining intent [of the resident] can be difficult. Many times, intent is not communicated in writing, or even orally, and can only be inferred by facts and circumstances…[t]he best evidence of a resident's 'intent' is where the resident goes after a clinical base year."

Response: We agree with the commenter that "intent" of the resident can indeed be difficult for us to determine, which is, in part, why our policy has been based upon the first, or initial, program in which the resident trains, (which can be determined and documented). We disagree with the commenter that "[t]he best evidence of a resident's intent is where the resident goes after a clinical base year," because we believe the best evidence of a resident's intent is the program in which the resident actually trains in the first year of residency. After significant deliberation and reflection on the comments, we also believe documentation that a resident has matched simultaneously for a first year of generalized training and a specialty program that begins thereafter is also sufficient evidence of a resident's intent to continue training in the specialty program, and not in the specialty associated with the generalized clinical base year. Therefore, we are adopting as our final policy the policy that we solicited for comments in the proposed rule. Specifically, if a hospital can document that a resident matched simultaneously, we will determine the resident's IRP in the first year based upon the period of board eligibility for the specialty program the resident had "matched" to enter in the second year.

Comment: We received one comment that cited the language in section 1886(h)(5)(F) of the Act: "enters the residency program" (emphasis added by the commenter) as evidence that the statute allows CMS to establish the IRP in the second training year in all cases. The commenter stated that the statutory language "can just as easily be interpreted as referring to entering [the longer, specialty program] as to entering the clinical base year or transitional year."

Response: With this final rule, we are changing our policy regarding the determination of the IRP for residents that match simultaneously for a clinical base year and subsequent specialty program. Specifically, if hospitals can document that a resident matched simultaneously, we will determine the resident's IRP in the first year based upon the period of board eligibility for the specialty program the resident is "matched" to enter in the second year. We do not believe we always wait to establish a resident's IRP in the second year of training when a resident will have "entered" a residency training program in the first year. Where there is no documentation available in the first year of training to demonstrate that a resident intends to continue training, after completing the first year, in a different medical specialty and, ultimately, to obtain board certification in that specialty, we continue to believe it is appropriate to assign the IRP based on the specialty associated with the first year of residency training.

Comment: We received one comment that noted that the proposed rule did not include an implementation date.

Response: We are stating in this final rule that the implementation date for the policy change regarding the initial residency period for "simultaneous match" residents is for portions of cost reporting periods occurring on or after October 1, 2004.

Comment: One commenter implied that CMS should not consider the costs of the proposed IRP policy as estimated by CMS in the proposed rule in determining whether the proposal should be finalized, since CMS did not account for all of the factors that may serve to offset some of the costs of the proposed IRP policy. For instance, the commenter said that CMS did not take into account the savings resulting from the

proposal to require that the non-primary care PRA be applied by hospitals to residents training in their clinical base year and for the duration of their training in that specialty. The commenter added that savings could result from the application of the possible "simultaneous match" policy to residents who begin their training in a specialty such as surgery, which requires a minimum of five years for board eligibility, and subsequently pursue training in a specialty that requires four years of training for board eligibility, since these residents would actually see a decrease in the number of years in which they would be weighted at 1.0 FTE under the proposed policy. The commenter also recommended that, rather than comparing the present costs of direct GME payments to the projected costs subsequent to implementation of the policy, CMS should compare the projected costs of not implementing the policy against the projected costs resulting from implementation. The commenter believed that the incremental difference between implementation and non-implementation of the proposed policy is likely far smaller than estimated in the proposed rule since, even if CMS were not to implement the policy under consideration, hospitals would now be aware of the current policy, which would lead to an increase in positions in transitional year programs.

Response: We acknowledge the points raised by the commenter, but note that the commenter's concerns are moot since, as explained in response to previous comments, we have decided to adopt the "simultaneous match" policy as final in this final rule.

c. Exception to Initial Residency Period for Geriatric Residency or Fellowship Programs (Section 712 of Pub. L. 108-173 and Redesignated §413.79(a) (a redesignation of existing §413.86(g)(1))

As explained further below, under Medicare direct GME payment rules, the initial residency period is generally defined as the minimum number of years of training required for a resident to become board eligible in a specialty (not to exceed 5 years) and is established at the time the resident enters his or her first training program. For purposes of direct GME payments, a resident's full-time equivalent (FTE) training time is weighted at 1.0 during the initial residency period and 0.5 for training that continues beyond the initial residency period. Section 1886(h)(5)(F) of the Act generally limits a resident's initial residency period to no longer than 5 years. That section also provides an exception that allows FTE training time spent by residents in an approved geriatric residency program to be treated as part of the resident's initial residency period, that is, weighted at 1.0 FTE for up to an additional 2 years after conclusion of the otherwise applicable initial residency period.

We understand, based on information provided by the American Geriatric Society (AGS), that in 1998, the American Board of Internal Medicine and the American Board of Family Physicians (hereinafter "the Boards") reduced the minimum number of years of formal training required for residents to become board eligible in geriatrics from 2 years to 1 year. As a result, the initial residency period, and full direct GME funding for residents in geriatric training programs, would be limited to 1 year.

However, we understand that many teaching hospitals continue to run geriatric residency or fellowship programs of at least 2 years in length (some are even 3 years). We also understand that, despite the decrease in the minimum requirements for board eligibility, the Accreditation Council for Graduate Medicare Education (ACGME)

continues to accredit some geriatric training programs for the full duration of the fellowships. For example, if a hospital's geriatric fellowship is 3 years in length, the program may continue to be accredited by the ACGME for the full 3 years, but the FTE time spent by a resident training in the geriatric program would be weighted at 1.0 for the first year of the resident's training and at 0.50 for the second and third year of the fellowship. (However, we note that FTE residents' time is not weighted for purposes of IME payments.)

Effective October 1, 2003, section 712 (a) of Pub. L. 108-173 clarified that Congress intended to provide an exception to the initial residency period for purposes of direct GME payments for geriatric residency or fellowship programs such that "where a particular approved geriatric training program requires a resident to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatric training program are treated as part of the resident's initial residency period, but are not counted against any limitation on the initial residency period." Therefore, in the May 18, 2004 proposed rule (69 FR 28312), we proposed that, effective for cost reporting periods beginning on or after October 1, 2003, if a resident is training in an accredited geriatric residency or fellowship program of 2 (or more) years in duration, hospitals may treat training time spent during the first 2 years of the program as part of the resident's initial residency period and weight the resident's FTE time at 1.0 during that period, regardless of the fact that the minimum number of years of training required for board eligibility in geriatrics is only 1 year. We noted that the statutory language quoted above does not allow a hospital to treat time spent by a resident in the second year

of geriatric training as part of the resident's initial residency period in the case where the resident trained in a geriatric residency or fellowship program that is accredited as a 1-year program because, in that case, the resident could be board eligible after only 1 year of training.

Even though the Congress gave the Secretary authority to implement section 712 of Pub. L. 108-173 through an interim final rule with comment period, we chose to provide instructions in a One-Time Notification (OTN) to fiscal intermediaries and providers (Transmittal 61, CR 3071), "Changes to the FY 2004 Graduate Medical Education (GME) Payments as Required by the Medicare Modernization Act of 2003 (MMA), P.L. 108-173," issued on March 12, 2004, and indicated in the proposed rule that we are implementing the statutory provision in our regulations through the notice and comment rulemaking process. We proposed to revise proposed redesignated §413.79(a) (a redesignation of §413.86(g)(1)) to incorporate the provision of section 712(a) of Pub. L. 108-173. We received no comments on this proposed change in regulation. Therefore, we are adopting the proposed regulation without modification.

4. Per Resident Amount: Extension of Update Limitation on High-Cost Programs (Section 711 of Pub. L. 108-173 and §413.77(d)(2)(iii)(B)(3) (a redesignation of existing §413.86(e)(4)(ii)(C)(2)(iii)))

Section 1886(h)(2) of the Act, as amended by section 311 of the Balanced Budged Refinement Act (BBRA) of 1999 (Pub. L. 106-113), establishes a methodology for the use of a national average per resident amount (PRA) in computing direct GME payments for cost reporting periods beginning on or after October 1, 2000, and on or before

September 30, 2005. Generally, section 1886(h)(2)(D)(ii) of the Act establishes a "floor" for hospital-specific PRAs at 70 percent of the locality-adjusted national average PRA. In addition, section 1886(h)(2)(D)(iv) of the Act establishes a "ceiling" that limits the annual adjustment of a hospital-specific PRA if the PRA exceeded 140 percent of the locality-adjusted national average PRA. Section 511 of the Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106-554) further amended section 1886 (h)(2) of the Act to increase the floor that was established by the BBRA to 85 percent of the locality-adjusted national average PRA. For purposes of calculating direct GME payments, each hospital-specific PRA is compared to the floor and ceiling to determine whether the hospital-specific PRA should be revised. (We direct readers to Program Memorandum A-01-38, March 21, 2001 for historical reference on calculating the floor and ceiling.)

Section 711 of Pub. L. 108-173 amended section 1886 (h)(2)(D)(iv) of the Act to freeze the annual CPI-U updates to hospital-specific PRAs for those PRAs that exceed the ceiling for FYs 2004 through 2013. Therefore, in the May 18, 2004 proposed rule (69 FR 28313), we proposed that, for cost reporting periods beginning during FY 2004 through FY 2013, we would calculate a ceiling that is equal to 140 percent of the locality-adjusted national average PRA for each hospital and compare it to each hospital-specific PRA. If the hospital-specific PRA for the preceding year is greater than 140 percent of the locality-adjusted national average PRA "ceiling" in the current fiscal year, the hospital-specific PRA for the current year is frozen at the preceding fiscal year’s hospital-specific PRA and is not updated by the CPI-U factor. We note that a hospital may have

more than one PRA. Each of a hospital's PRAs must be separately compared to the "ceiling" PRA to determine whether that PRA should be frozen at the level for the previous year or updated by the CPI-U factor.

For example, to determine the applicable PRA for a cost reporting period beginning during FY 2004, we proposed to compare the hospital-specific PRA from the cost reporting period that began during FY 2003 to the FY 2004 locality-adjusted national average PRA for that hospital. If the FY 2003 hospital-specific PRA exceeds 140 percent of the FY 2004 locality-adjusted national average PRA, the FY 2004 hospital-specific PRA is frozen at the level of the FY 2003 hospital-specific PRA and is not updated by the CPI-U factor for FY 2004.

Due to the effective date of the statutory provision of section 711 of Pub. L. 108-173, we issued a notification to fiscal intermediaries and providers regarding the provision in the OTN issued on March 12, 2004 (Transmittal 61, CR 3071). In the May 18, 2004 proposed rule, to incorporate the changes made by section 711 of Pub. L. 108-173 in our regulations regarding the determination of PRAs, we proposed to: (1) revise proposed redesignated §413.77(d)(2)(iii)(B)(3) (a proposed redesignation of existing §413.86(e)(4)(ii)(C)(2)(iii)) to make it applicable only to FY 2003; (2) further redesignate proposed newly redesignated §413.77(d)(2)(iii)(B)(4) (the proposed redesignation of existing §413.86(e)(4)(ii)(C)(2)(iv)) as §413.77(d)(2)(iii)(B)(4); and (3) add a proposed new §413.77(d)(2)(iii)(B)(4).

Comment: One commenter stated that many hospitals incur direct GME costs beyond those reimbursed by Medicare through the PRA due to the difficulties in

recruiting physicians to certain areas and the shortages of physicians in certain specialty programs. The commenter stated that the freeze in the inflation updates to the per resident amounts will inhibit a hospital from providing high quality education, and will result in additional physician shortages.

Response: The commenter is referring to section 711 of Pub. L. 108-173 that freezes the annual CPI-U updates to hospital-specific PRAs for those PRAs that exceed the ceiling for FYs 2004 through 2013. While we are sympathetic to the commenter's concerns, this provision is statutory and must be implemented as mandated.

5. Residents Training in Nonhospital Settings

a. Background

With respect to reimbursement of direct GME costs, since July 1, 1987, hospitals have been allowed to count the time residents spend training in sites that are not part of the hospital (referred to as "nonprovider" or "nonhospital sites") under certain conditions. Section 1886(h)(4)(E) of the Act requires that the Secretary's rules concerning computation of FTE residents for purposes of direct GME payments "provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting." (Section 1886(h)(4)(E) of the Act, as added by section of 9314 of the Omnibus Budget Reconciliation Act of 1986, Pub. L. 99-509.)

Regulations regarding time spent by residents training in nonhospital sites for purposes of direct GME payment were first implemented in the September 29, 1989 final rule (54 FR 40286). We stated in that rule (under §413.86(f)(3)) that a hospital may count the time residents spend in nonprovider settings for purposes of direct GME payment if the residents spend their time in patient care activities and there is a written agreement between the hospital and the nonprovider entity stating that the hospital will incur all or substantially all of the costs of the program. The regulations at that time defined "all or substantially all" of the costs to include the residents' compensation for the time spent at the nonprovider setting.

Prior to October 1, 1997, for IME payment purposes, hospitals could only count the time residents spend training in areas subject to the IPPS and outpatient areas of the hospital. Section 4621(b)(2) of the BBA of 1997 (Pub. L. 105-33) revised section 1886(d)(5)(B) of the Act to allow providers to count time residents spend training in nonprovider sites for IME purposes, effective for discharges occurring on or after October 1, 1997. Specifically, section 1886(d)(5)(B)(iv) of the Act was amended to provide that "all the time spent by an intern or resident in patient care activities under an approved medical residency program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting."

In the regulations at §§412.105(f)(1)(ii)(C) and 413.86(f)(4) (as issued in the July 31, 1998 **Federal Register**), we specify the requirements a hospital must meet in order to include the time spent by a resident training in a nonhospital site in its FTE count

for Medicare reimbursement for portions of cost reporting periods occurring on or after January 1, 1999 for both direct GME and for IME payments. The regulations at §413.86(b) redefine "all or substantially all of the costs for the training program in the nonhospital setting" as the residents' salaries and fringe benefits (including travel and lodging where applicable), and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct GME. A written agreement between the hospital and the nonhospital site is required before the hospital may begin to count residents training at the nonhospital site; the agreement must provide that the hospital will incur the costs of the resident's salary and fringe benefits while the resident is training in the nonhospital site. The hospital must also provide reasonable compensation to the nonhospital site for supervisory teaching activities, and the written agreement must specify that compensation amount.

b. Moratorium on Disallowances of Allopathic or Osteopathic Family Practice Residents Training Time in Nonhospital Settings (Section 713 of Pub. L. 108-173 and Redesignated §413.78 (a redesignation of existing §413.86(f))

As we mentioned above, under existing §413.86(f)(4), for portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonhospital settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the hospital's number of FTE residents for purposes of calculating both direct GME and IME payments, if the following conditions are met:

(1) The resident spends his or her time in patient care activities.

(2) There is a written agreement between the hospital and the nonhospital site that indicates that the hospital will incur the costs of the resident's salary and fringe benefits while the resident is training in the nonhospital site, and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(3) The hospital incurs "all or substantially all" of the costs for the training program in the nonhospital setting. "All or substantially all" means the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education.

In order for the hospital to incur "all or substantially all" of the costs in accordance with the regulations, the actual cost of the time spent by teaching physicians in supervising residents in the nonhospital setting must be compensated by the hospital. The amount of supervisory GME costs is dependent upon the teaching physician's salary and the percentage of time that he or she devotes to activities related to the residency program at the nonhospital site. As long as there are supervisory costs associated with the nonhospital training, the hospital must reimburse the nonhospital setting for those costs in order to count FTE resident time spent in the nonhospital site for purposes of IME and direct GME payments.

Many hospitals have entered into written agreements with teaching physicians that state that the teaching physician is "volunteering" his or her time in the nonhospital

site, and, therefore, the hospital is not providing any compensation to the teaching physician. Other hospitals have paid only a nominal amount of compensation for the supervisory teaching physicians' time in the nonhospital setting. Because the existing regulations at §413.86(f)(4) state that the hospital must incur all or substantially all of the direct GME costs, including those costs associated with the teaching physician, regardless of whether the written agreement states that the teaching physician is "volunteering," we have required that the hospital must pay these costs in order to count FTE residents training in the nonhospital site, as long as these teaching physician costs exist.

However, during the 1-year period from January 1, 2004 through December 31, 2004, section 713 of Pub. L. 108-173, through a moratorium, allows hospitals to count allopathic or osteopathic family practice residents training in nonhospital settings for IME and direct GME purposes, without regard to the financial arrangement between the hospital and the teaching physician practicing in the nonhospital setting to which the resident is assigned. We implemented section 713 in the One-Time Notification (OTN), "Changes to the FY 2004 Graduate Medical Education (GME) Payments as Required by the Medicare Modernization Act of 2003 (MMA)" (CR 3071, Transmittal 61, issued on March 12, 2004). Generally, to implement the provisions of section 713, we stated in the OTN that, when settling prior year cost reports during this 1-year period, or for family practice residents actually training in nonhospital settings during this 1-year period, the fiscal intermediaries should allow the hospitals to count allopathic and osteopathic family practice residents training in the nonhospital

setting for direct GME and IME payment purposes without regard to the financial arrangement between the hospital and the nonhospital site pertaining to the teaching physicians' costs associated with the residency program.

(1) Cost Reports That Are Settled Between January 1, 2004 and December 31, 2004

When fiscal intermediaries settle cost reports during January 1, 2004 through December 31, 2004 (Calendar Year (CY) 2004), a hospital that seeks to count allopathic or osteopathic family practice FTE residents training in a nonhospital setting(s) is allowed to count those FTEs for IME and direct GME purposes, even in instances where the written agreement between the hospital and a teaching physician or a nonhospital site does not mention teaching physician compensation, specifies only a nominal amount of compensation, or states that the teaching physician is "volunteering" his or her time training the residents. For example, when a fiscal intermediary is settling a cost report during CY 2004 that has a fiscal year end of June 30, 2001, the fiscal intermediary will allow the hospital to count family practice FTE residents that trained in a nonhospital setting during the period covered by the June 30, 2001 cost report, regardless of the financial arrangement in place between the hospital and the teaching physician at the nonhospital site during the period covered by the June 30, 2001 cost report.

We note that this moratorium does not apply to cost reports that are not settled during January 1 through December 31, 2004, that do not coincide with, or overlap, the January 1 through December 31, 2004 period. For example, if a cost report for fiscal year ended December 31, 2003 (or June 30, 2003, or others) is not settled during the January 1 through December 31, 2004 period, the moratorium would not apply.

Comment: One commenter expressed concern with the implementation of the moratorium on disallowances of allopathic or osteopathic family practice residents' training time in nonhospital settings. Specifically, the commenter was concerned that fiscal intermediaries may purposely delay audits or the issuance of settled cost reports to avoid the impact of the moratorium. The commenter requested CMS to clearly and firmly direct fiscal intermediaries to settle all cost reports in 2004 that they otherwise would settle and inform intermediaries that they may not take the moratorium into account in determining whether and when to settle cost reports.

Response: We have already addressed the issue of how fiscal intermediaries are to implement this moratorium. In Change Request 3071, Pub. 100-20, Transmittal No. 61, issued to the fiscal intermediaries on March 12, 2004, we stated that, "Scheduling of cost report audit or settlement activities during calendar year 2004 should be done in accordance with normal procedures. If, since January 1, 2004, but before issuance of this OTN, you have settled cost reports and did not allow hospitals to count family practice residents at nonhospital sites where the hospitals did not pay for all of the teaching physician costs, then review such settlements and, if appropriate, reopen and reverse the disallowance. If, as of issuance of this OTN, you have disallowed such residents in the process of settling a cost report, but have not yet issued the Notice of Program Reimbursement (NPR), then reverse the disallowance of those residents. Cost reports that have already been settled prior to January 1, 2004 should not be reopened to allow a hospital to count family practice residents at nonhospital sites where the hospital did not pay for all of the teaching physician costs, even if requested by a hospital."

Therefore, scheduling of audit or settlement activities should be done using normal procedures. Given the above instruction, fiscal intermediaries should not take the moratorium into consideration or delay settlement and audit activities. Because we have instructed fiscal intermediaries to follow normal procedures, we request that hospitals respect our instructions and refrain from pressuring fiscal intermediaries to settle more cost reports than they would during the normal course of business in an attempt to take advantage of this moratorium.

(2) Family Practice Residents That Are Training in Nonhospital Settings Between January 1, 2004 and December 31, 2004.

In addition to allowing family practice residents that trained in nonhospital settings to be counted in cost reports that the fiscal intermediaries settle during the period of January 1, 2004 through December 31, 2004, without regard to the financial arrangements between the hospital and the teaching physician at the nonhospital site, the fiscal intermediaries are to allow family practice residents that actually are or will be training in nonhospital settings during January 1, 2004, through December 31, 2004, without regard to the financial arrangements between the hospital and the teaching physician at the nonhospital site. That is, when fiscal intermediaries settle cost reports that cover service periods of January 1, 2004 through December 31, 2004, a hospital that seeks to count allopathic or osteopathic family practice FTE residents training in a nonhospital setting(s) would be allowed to count those FTEs, even in instances where the written agreement between the hospital and a teaching physician or a nonhospital site does not mention teaching physician compensation, specifies only a nominal amount of

compensation, or states that the teaching physician is "volunteering" his or her time training the residents. If a hospital has a fiscal year that is other than a calendar year, the hospital may count the family practice residents training in the nonhospital setting during those portions of its fiscal years that fall within the January 1, 2004 and December 31, 2004 period. For example, when a fiscal intermediary is settling a hospital's June 30, 2004 cost report, the hospital would be allowed to count family practice FTE residents that trained in a nonhospital setting during the period of January 1, 2004 through June 30, 2004, regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital site from January 1 through June 30, 2004. Similarly, when a fiscal intermediary settles the hospital's June 30, 2005 cost report, the hospital would be allowed to count family practice FTE residents that trained in a nonhospital setting during the period of July 1, 2004 through December 31, 2004, regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital site from July 1 through December 31, 2004. (However, we note that family practice residents that train in nonhospital settings beginning January 1, 2005, and after are not subject to the moratorium provided under section 713 of Pub. L. 108-173.)

Because we are interpreting this moratorium to apply to prior period cost reports that are settled during calendar year (CY) 2004, and to cost reports that are settled after CY 2004 that cover training that occurred during the period of January 1, 2004 through December 31, 2004, a gap in applicability of the moratorium may result for family practice residents training in nonhospital settings. For example, a hospital might be

permitted to count certain FTE family practice residents that are included in its FY 2001 cost report in accordance with the moratorium because that cost report is settled during CY 2004. However, the hospital might not be permitted to count certain FTE family practice residents in its FY 2002 and FY 2003 cost reports because these cost reports would not be settled during CY 2004 and the moratorium would not apply. The hospital then could be permitted to count certain FTE family practice residents in its FY 2004 cost report in accordance with the moratorium, because the FY 2004 cost report would contain family practice residents who actually trained in a nonhospital setting during CY 2004.

Regardless of whether the fiscal intermediaries are settling prior period cost reports during CY 2004, or settling cost reports after CY 2004 that cover training during the period of January 1, 2004 through December 31, 2004, we emphasize that the moratorium provided in section 713 of Pub. L. 108-173 only applies for purposes of counting FTE residents in allopathic and osteopathic general family practice programs that were in existence (that is, training residents) as of January 1, 2002 and where the requirement to incur the teaching physician compensation related to direct GME may not have been met. Therefore, in the May 18, 2004 proposed rule (69 FR 28315), for residents training in nonhospital settings, we proposed that the moratorium applies only: (1) to FTE residents in general family practice programs (and not to dental, podiatric, or other allopathic or osteopathic specialty programs); (2) to family practice programs that were in existence as of January 1, 2002; and (3) with the exception of teaching physician compensation, to training in nonhospital settings that meet the requirements in the existing regulations at §413.86(f)(4) (proposed to be redesignated as §413.78(d)).

We did not proposing any regulation text changes to address this provision in the proposed rule. We note that section 713(b) of Pub. L. 108-173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and may consider additional policy and regulation changes at that time if they are warranted.

Comment: Many commenters expressed strong opposition to CMS' policy regarding IME and DGME payments for residents training at a nonhospital setting(s). The commenters believe that the requirement that hospitals pay supervising physicians in nonhospital settings for the salary and fringe benefits that is attributable to the time spent teaching residents is severely detrimental to residency programs that depend on nonhospital training and runs counter to long-standing traditions prevalent in physician education.

Several commenters stated that there is inconsistency in the treatment of supervisory costs in nonhospital settings by CMS and fiscal intermediaries and requested clarification regarding CMS policy regarding compensation of supervisory physicians who "volunteer" their time to train residents in a nonhospital setting.

Several commenters proposed that CMS clarify in the final rule that where supervising physicians freely agree to volunteer their time and the hospital pays all other

training costs (residents' salaries, benefits, and other training costs) that the hospital has incurred "all or substantially all" of the costs of the program.

Several commenters urged CMS to extend the MMA moratorium on disallowances of allopathic or osteopathic family practice residents training time in nonhospital settings (redesignated §413.78) to cover all current, prior, and future nonhospital education. Another commenter believes that this moratorium should not be limited to Family Practice residents, but rather should cover any residents that train in nonhospital settings.

Response: While we sympathize with the commenter's concerns, the cost reporting period specified for the moratorium on disallowances of allopathic or osteopathic family practice residents training time in nonhospital settings is set by Section 713 of Pub. L. 108-173. Furthermore, we have no discretion to expand the moratorium to residency programs other than Family Practice. Many hospitals have claimed that the teaching physician is "volunteering" his or her time in the nonhospital site, and, therefore, the hospital is not providing any compensation to the teaching physician. The redesignated regulation at §413.78 states that the hospital must incur all or substantially all of the direct GME costs. This requirement included those costs associated with the teaching physician, regardless of whether the written agreement states that the teaching physician is "volunteering." The statute and our regulations require that the hospital must pay the costs of training residents at the nonhospital site in order to count FTE residents training at that site including teaching physician costs, as long as these teaching physician costs exist. We did not propose any regulation text changes that

address these supervisory costs of training residents at nonhospital setting(s). Section 713(b) of Pub. L. 108-173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to the Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and may consider additional policy, regulation changes, and instructions to financial intermediaries at that time if they are warranted.

Comment: One commenter believes that there is unmeasured monetary value afforded to nonhospital sites that are training residents and that supervisory costs should be compared to what nonhospital sites gain as a result of training residents. For example, "off-site locations may also have reduced clinical staff hours, as some of the work delegated to residents is similar or identical to what might be……work normally performed by clinical staff in offices without residents." The commenter believes compensation for supervising physicians that does not take into account these economic benefits would result in a "gross overpayment" to nonhospital sites.

Response: In order to count residents training at nonhospital sites, for purposes of direct and indirect GME payments, the statute requires a hospital to pay the nonhospital site for all or substantially all of the costs for the training program in that setting. Although we understand that a benefit does accrue to the nonhospital site because there is GME training being conducted at that site, a determination of the cost of the training must be made and the hospital must pay the nonhospital site for those costs. We are not

proposing to make any changes regarding compensation for supervising physicians at nonhospital sites at this time. As stated above, section 713(b) of Pub. L. 108-173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to the Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector General's report and will consider the possibility of policy and regulation changes at that time if warranted.

Comment: Many commenters proposed that CMS "make very clear in regulation or intermediary instruction that if there are no payments made to the non-hospital site by the hospital, that is not an a priori reason to deny time spent by residents in that environment. If the hospital is paying the residents' salary and benefits, travel costs, lodging, etc., there may in fact be no costs (hence payments) to the non-hospital site. This would frequently be the case in situations where the preceptor is volunteering his/her teaching or supervisory time."

Response: We did not propose any changes in policy concerning this issue. We note that Section 713(b) of Pub. L. 108-173 directs the Inspector General of the Department of Health and Human Services to conduct a study of the appropriateness of alternative methodologies for payment of residency training in nonhospital settings and to submit a report to the Congress on the results of the study, along with recommendations, as appropriate, by December 8, 2004. We will await the release of the Inspector

General's report and will consider additional policy, regulation changes, and instructions to financial intermediaries at that time if warranted.

c. Requirements for Written Agreements for Residency Training in Nonhospital Settings (Redesignated §413.78 (a redesignation of existing §413.86(f))

As mentioned above, under section 1886(h)(4)(E) of the Act, a hospital may count residents training in nonhospital settings for direct GME purposes (and under section 1886(d)(5)(B)(iv) of the Act, for IME purposes), if the residents spend their time in patient care activities and if ". . . the hospital incurs all, or substantially all, of the costs for the training program in that setting." We believe the Congress intended to facilitate residency training in nonhospital settings by requiring hospitals to commit to incur, and actually incur, all or substantially all of the costs of the training programs in the nonhospital sites. Accordingly, in implementing section 1886(h)(4)(E) of the Act, first in the regulations at §413.86(f)(3), effective July 1, 1987, and later at §413.86(f)(4), effective January 1, 1999, we required that, in addition to incurring all or substantially all of the costs of the program at the nonhospital setting, there must be a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting. The later regulations further specify that the written agreement must indicate the amount of compensation provided by the hospital to the nonhospital site for supervisory teaching activities. (In the May 18, 2004 proposed rule, we noted that §413.86(f)(3) was proposed to be redesignated as §413.78(c), and §413.86(f)(4) was proposed to be redesignated as §413.78(d).)

We required the written agreements in regulations in order to provide an administrative tool for use by the fiscal intermediaries to assist in determining whether hospitals would incur all or substantially all of the costs of the training in the nonhospital setting in accordance with Congressional intent. Furthermore, our policy has required that the written agreement between the hospital and the nonhospital site be in place prior to the time that the hospital begins to count the FTE residents training in the nonhospital site. A written agreement signed before the time the residents begin training at the nonhospital site that states that the hospital will incur the costs of the training program at the nonhospital site indicates the hospital's ongoing commitment to incur the costs of training at that site.

In settling cost reports where hospitals have included residents training at nonhospital sites in their FTE count, the fiscal intermediaries have encountered numerous situations where hospitals have complied with the requirement to incur all or substantially all of the costs of training in nonhospital settings. However, despite our longstanding regulations that state the requirement for a written agreement, these hospitals have not met the regulatory requirements related to written agreements. For example, some hospitals had no written agreement in place during the training in the nonhospital setting, or written agreements were not timely (that is, they were prepared after the residents began or, in some cases, finished training at the nonhospital site), or the agreements did not include a specific amount of compensation to be provided by the hospital to the nonhospital site for supervisory teaching activities. As a result, hospitals have faced disallowances of direct GME and IME payments relating to FTE residents training in

nonhospital settings because the hospitals did not comply with the regulatory requirements concerning written agreements.

In retrospect, we believe the regulatory requirements concerning the written agreements may not have been the most efficient aid to fiscal intermediaries in determining whether hospitals would actually incur all or substantially all of the costs of the training programs in nonhospital settings. The fiscal intermediaries have been required to ensure that hospitals are complying with the regulations regarding written agreements, in addition to determining whether a hospital actually incurred the appropriate costs. We believe it would be more appropriate and less burdensome for both fiscal intermediaries and hospitals if we instead focus the fiscal intermediaries' reviews on the statutory requirement that hospitals must incur all or substantially all of the costs of the program in the nonhospital setting. Therefore, in the May 18, 2004 proposed rule (69 FR 28315), we proposed to revise the regulations under proposed new §413.78 (a proposed redesignation of existing §413.86(f)) to remove the requirement for a written agreement between the hospital and the nonhospital setting as a precondition for a hospital to count residents training in nonhospital settings for purposes of direct GME and IME payments. However, consistent with our belief that the Congress intended that hospitals commit to incur, and actually incur, all or substantially all of the costs of the training programs in the nonhospital sites in order to facilitate training at nonhospital sites, we are also proposing that, in order for the hospital to count residents training in a nonhospital setting, the hospital must pay for the nonhospital site training costs concurrently with the training that occurs during the cost reporting period.

We understand that residents' rotations, including those to nonhospital settings, are generally in discrete blocks of time (for example, 4-week or 6-week rotations). Therefore, to account for various rotation lengths, we proposed under the new proposed §413.78(e) that, in order to count residents training in a nonhospital setting, a hospital must pay all or substantially all of the costs of the training in a nonhospital setting(s) by the end of the month following a month in which the training in the nonhospital site occurred. If a hospital is counting residents training in a nonhospital setting for direct GME and IME purposes in any month of its cost reporting period, the hospital must make payment by the end of the following month to cover all or substantially all of the costs of training in that setting attributable to the preceding month. If the residents are employed by the hospital, and receive their salary payments (and fringe benefits) every 2 weeks, the hospital may continue to pay the residents' salaries every 2 weeks during the residents' rotation to the nonhospital setting. This should still result in payment being made for residents' time spent in nonhospital settings by the end of the following month. (We also note that the hospital must pay travel and lodging expenses, if applicable.) We proposed that the hospital would be required to pay the nonhospital site for the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct GME by the end of the month following the month in which the training in the nonhospital setting occurred. We proposed that if a hospital does not pay for all or substantially all of the costs of the program in the nonhospital setting by the end of the month following the month in which the training occurred, the hospital could not count those FTE residents in the month that the training occurred. Therefore, we proposed to determine if residents

training in nonhospital sites should be counted on a month-to-month basis, depending on whether a hospital paid for the training costs of those residents by the end of the month following the month in which the training occurred.

The following are examples of how a hospital that sends residents to train in nonhospital sites would make payments concurrently with the nonhospital site training:

- Example 1. Hospital A, with a fiscal year end (FYE) of December 31, trains 10 internal medicine residents and 6 family practice residents. Each January, April, July, and October, Hospital A sends 5 internal medicine FTE residents to the Physicians' Clinic for 4 weeks. Each month, Hospital A sends 2 family practice FTE residents to the Family Clinic. The residents are employed by Hospital A, and the residents receive fringe benefits from and are paid every 2 weeks by Hospital A, regardless of whether they are training in Hospital A or at a nonhospital site. In order to make payments concurrently with the training that is occurring in the nonhospital sites, Hospital A must pay the Physicians' Clinic by the end of February, May, August, and November, respectively, of each cost reporting year, to cover the costs of teaching physician compensation and fringe benefits attributable to direct GME. Similarly, because residents are training at the Family clinic each month, Hospital A must pay the Family Clinic by the end of each month for the previous month's costs of teaching physician compensation and fringe benefits attributable to direct GME. There are no travel and lodging costs associated with these rotations to nonhospital sites.

- Example 2. University A will sponsor an ophthalmology program with eight residents beginning on July 1, 2005. The residents will be on the payroll of the

University, but they will train at Hospital B and at the University's Eye Clinic, which is a nonhospital setting. Hospital B has a June 30 FYE. Four of the residents will train in the Eye Clinic from August 1 to October 15, and the other four residents will train in the Eye Clinic from February 15 to April 30. Thus, residents are training in the Eye Clinic during the months of August, September, October, February, March, and April. If Hospital B wishes to count these FTE residents for IME and direct GME purposes in its cost reporting year ending June 30, 2006, and onward, it must pay the Eye Clinic at the end of September, October, November, March, April, and May, respectively, for the previous month's cost of the residents' salaries and fringe benefits, and the teaching physician compensation and fringe benefits attributable to direct GME.

- Example 3. Hospital C sends a resident to train at a nonhospital site from January 28 to February 20. The resident was employed by the nonhospital site during this time. Hospital C paid the nonhospital site for the cost of the resident's salary and fringe benefits and the teaching physician compensation and fringe benefits attributable to direct GME by February 28 to account for the training that occurred from January 28 through January 31. However, Hospital C did not pay the nonhospital site by March 31 to account for the training that occurred in February. Therefore, Hospital C could not count the resident's time in the nonhospital setting from February 1 through February 20 for direct GME and IME purposes.

We note that our proposal to require hospitals to pay for the nonhospital site training costs concurrently with the training that occurs in the nonhospital site was a departure from our current policy concerning the timeframe in which a hospital must

make payment for the training costs. Currently, we apply the existing regulations at §413.100(c)(2)(i), which state that a short-term liability (such as the hospital's obligation to pay the nonhospital site for the residency training costs) must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. However, because we are proposing to no longer require that a written agreement between the hospital and the nonhospital site be in place prior to the time that the hospital begins to count the FTE residents training in the nonhospital site, we believe that a reasonable alternative to ensure that a hospital is facilitating the training at the nonhospital site through its ongoing commitment to incur all or substantially all of the costs is to require the hospital to make payments concurrently with the training that occurs in the nonhospital site in order to count the FTE residents for purposes of direct GME and IME payments.

We are aware that there are situations where, rather than providing direct financial compensation to the nonhospital site for supervisory teaching activities, the hospital is incurring all or substantially all of the teaching physician costs through nonmonetary, in-kind arrangements. In the May 18, 2004 proposed rule, we proposed that, in order to be considered concurrent with the nonhospital site training, in-kind arrangements must be provided or made available to the teaching physician at least quarterly, to the extent that there are residents training in a nonhospital setting(s) in a quarter.

We proposed to revise §413.86(f) (proposed to be redesignated as §413.78 in this proposed rule) to add a new paragraph (§413.78 (e)) to state that a hospital must incur all or substantially all of the costs of training in a nonhospital setting by the end of the month

following a month in which the training in the nonhospital site occurred, to the extent that there are residents training in a nonhospital setting in a month. This proposed change would be effective for portions of cost reporting periods occurring on or after October 1, 2004. We proposed to revise paragraph (d) of the proposed redesignated §413.78 to reflect the effective cost reporting periods of the provisions under the new paragraph (e).

Comment: Many commenters voiced strong opposition to the proposed regulation that requires hospitals to pay for all or substantially all of the costs of training residents at the nonhospital setting(s) by the end of the month following a month in which the training in the nonhospital setting(s) occurred. The commenters believe that this proposed regulation would not be less burdensome than the existing system and indeed would increase the administrative burdens to hospitals and intermediaries alike.

Response: As we stated in the May 18, 2004 proposed rule, we believe the Congress intended to facilitate residency training in nonhospital settings by requiring hospitals to commit to incur, and actually incur, all or substantially all of the costs of the training programs in the nonhospital sites. Accordingly, in implementing section 1886(h)(4)(E) of the Act, first in the regulations at §413.86(f)(3), effective July 1, 1987, and later at §413.86(f)(4), effective January 1, 1999, we required that, in addition to incurring all or substantially all of the costs of the program at the nonhospital setting, there must be a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting.

In the May 18, 2004 proposed rule, we indicated our belief that it would be more appropriate and less burdensome for both fiscal intermediaries and hospitals if, instead of focusing on the written agreement, we focus on the statutory requirement that hospitals must incur all or substantially all of the costs of the program in the nonhospital setting. Therefore, we proposed to remove the requirement for a written agreement between the hospital and the nonhospital setting as a precondition for a hospital to count residents training in nonhospital settings for purposes of direct GME and IME payments. Instead, we proposed that, in order to count residents training in a nonhospital setting, a hospital must pay all or substantially all of the costs of the training in a nonhospital setting(s) by the end of the month following a month in which the training in the nonhospital site occurred. Payment of these costs by the end of the month following a month in which the training occurs would show an ongoing commitment to incur the cost of training residents at the nonhospital site and is consistent with the Congress' intent.

In response to the commenter's' concerns, we are revising the proposed finalized policy at §413.78 (a redesignation of §413.86(f)). We are concerned that hospitals may not always be able to comply with the timeframe for payment of nonhospital supervisory costs as indicated by the commenters. Therefore, we will allow hospitals to demonstrate their ongoing commitment to incur the costs of the training program in the nonhospital setting, and to count the FTE residents training thereby meeting at least *one* of the following criteria: (1) There is a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting. If the hospital chooses the written agreement option,

the existing requirements as specified in the regulations at §413.100(c)(2)(i) and §413.86(f)(4) would apply. Or, (2) the hospital pays the costs associated with the training program in the nonhospital setting(s) by the end of the *third* month following a month in which the training in the nonhospital setting(s) occurred. Allowing hospitals to choose between these two options and lengthening the required timeframe for concurrent payment of the costs of the training in a nonhospital site provides additional flexibility to hospitals and fiscal intermediaries while still ensuring compliance with the statutory requirement to demonstrate that hospitals will incur all or substantially all of the costs of the training program in the nonhospital setting.

Comment: Several commenters believe that our proposal to require hospitals to pay the costs of training residents at a nonhospital site by the end of the month following a month in which the training occurred is inconsistent with longstanding Medicare policy. They note that the regulations at §413.100(c)(2)(i) allow a hospital to recognize an accrued cost for Medicare payment purposes if it is paid within one year after the end of the cost reporting period in which the liability was incurred. Several commenters proposed that a hospital be considered to have incurred the cost of training residents in a nonhospital setting, with or without a written agreement, if this cost is paid in accordance with §413.100(c)(2)(i). One commenter proposed that a hospital be considered to have incurred the cost of training residents in a nonhospital setting, with or without a written agreement, if this cost is paid by the end of the month following the end of the cost reporting period.

Response: We agree that §413.100(c)(2)(i) permits a hospital to recognize an accrued cost for Medicare payment purposes if it is paid within one year after the end of the cost reporting period in which the liability was incurred. However, we have required a written agreement under our regulations in order to provide an administrative tool for use by the fiscal intermediaries to assist in determining whether hospitals would incur all or substantially all of the costs of the training in the nonhospital setting. As stated above, we are now allowing a hospital to choose how it will demonstrate that it will incur the nonhospital site training costs: either by executing a written agreement with the nonhospital site in accordance with existing regulations, or by concurrently paying the costs of training residents in the nonhospital setting (that is, by the end of the third month following the month in which the training occurred).

Comment: One commenter disagreed with CMS' policy requiring that the written agreement between a hospital and a nonhospital site be in place prior to residents commencing training at the nonhospital site. The commenter proposed that the written agreement be valid if in place at any time during the cost reporting year in which the training at the nonhospital site occurs.

Response: Regulations at 42 CFR 413.78 (previously §413.86(f)(4)) specify that there must be a written agreement between the hospital and the non-hospital site stating that the hospital will incur specific costs of training in the non-hospital site, including costs for supervisory teaching activities. It is our policy under that regulation that the written agreement between the hospital and non-hospital site be in place prior to the time that the hospital begins to count the FTE residents training in the non-hospital site. As

discussed earlier in this final notice, we are allowing a hospital to meet the requirement to pay all or substantially all of the costs of the program in the nonhospital setting, by either submitting a copy of the written agreement that was prepared prior to the residents' training or by documenting that payments were actually made within the required three month time period. We believe the new option for a hospital to demonstrate that it will incur the costs of a nonhospital site training program provides sufficient additional flexibility for providers. We are not adopting the commenter's proposal to allow hospitals to use a written agreement that is executed or submitted after the training has occurred. We do not believe allowing the written agreement to be put in place retrospectively, after resident training in the nonhospital site has commenced, would be consistent with our long-standing policy to demonstrate that the hospital will incur all or substantially all of the costs of the training program in the nonhospital site.

Comment: One commenter representing a particular medical specialty recommended that CMS use proof of program accreditation as evidence of a written agreement between hospitals and nonhospital settings. The commenter pointed out that written agreements between hospitals and nonhospital sites are required by the specialty's accreditation process. Therefore, the commenter added, time spent in these nonhospital sites is eligible for reimbursement.

Response: Under our existing regulations, the written agreement between a hospital and a nonhospital site must include several specific elements as follows:

- The hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site.

● The hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities.

● The agreement must indicate the compensation the hospital is providing for supervisory teaching activates.

We must be able to verify that the written agreement conforms to these requirements of the regulation. Therefore, the actual written agreement must be used as proof rather than using proof of the program's accreditation as a proxy, because the proof of accreditation may not include all of the required information specified at redesignated §413.78(d)(2).

Comment: One commenter requested that we place language in the regulations regarding the timing of nonmonetary compensation made available to supervising physicians that train residents in nonhospital settings. The commenter notes that while the preamble to the proposed rule addresses the timeframe for making in-kind compensation available to supervising physicians, the text of the regulations does not.

Response: The purpose of the preamble to a rule is to further explain, and often, to provide practical examples and guidance on the policy laid out in the regulation text. It would be highly impractical to address every specific circumstance to which our policies would apply in the text of our regulations. In this case, we believe the preamble to this final rule is sufficient to convey the policy regarding the timing of in-kind compensation made available to supervising physicians at nonhospital settings.

Comment: Several commenters asked for clarification regarding in-kind compensation for supervisory physicians in nonhospital settings. We proposed that in

order to be considered concurrent with the nonhospital site training, in-kind arrangements must be provided or made available to the teaching physician at least quarterly. The commenters asked that we elaborate on in-kind arrangements and give examples. The commenters also asked for examples of in-kind arrangements between a hospital and a solo physician that is training residents at a nonhospital site.

Response: There are situations where rather than providing direct financial compensation to the nonhospital site for supervisory teaching activities, the hospital is providing compensation through non-monetary, in-kind arrangements. If the hospital is using the written agreement option to show that it will incur all or substantially all of the cost of training residents in the nonhospital setting(s), our regulations require that the written agreement describe the arrangements that are involved. For example, the hospital may provide continuing education and other professional and educational support for supervising physicians in the nonhospital site in lieu of financial support. Another example of in-kind compensation is office space provided by the hospital to the supervising physician. The value of this space may be substituted for monetary compensation for teaching activities. This type of support must be described in the written agreement in lieu of a monetary amount for the hospital. If the hospital is opting to pay all or substantially all of the cost of training in the nonhospital setting(s) concurrently with the training that occurs during the cost reporting period, we had proposed that the in-kind arrangements must be provided or made available to the teaching physician at least quarterly, to the extent that there are residents training in a nonhospital setting(s) in a quarter. However, in order to make the policy regarding

monetary and in-kind compensation consistent, we are requiring in the final rule that in-kind compensation be provided or made available by the end of the *third* month following the month in which the training occurs.

We note further that, in the case of a solo practitioner, compensation at the practice is based solely and directly on the number of patients that the solo practitioner treats and for which the solo practitioner bills. Section 1886(h)(4)(E) of the Act requires that hospitals pay all or substantially all of the *cost* of training at the nonhospital site in order to count the FTE residents at that site. In this instance, we recognize that there are no costs associated with the supervisory teaching physician's time because the physician is not receiving compensation in any form or from any source while conducting teaching activities. Under these circumstances, we acknowledge that no direct or in-kind payment needs to be made to the supervising physician in order for the hospital to incur all or substantially all of the costs of the training program in the nonhospital setting, and to count the FTE residents' training time in the nonhospital setting.

Out of scope comments relating to GME:

Comment: Several comments addressed miscellaneous IME and direct GME issues, including accreditation of dental programs, , community education programs, community support, per resident amounts, the general application of affiliated groups, and redistribution of costs.

Response: We did not make any proposals relating to these issues in the May 18, 2004 proposed rule. Therefore, we decline to respond to these comments in this final rule. However, we will consider them for purposes of future rulemaking.

P. Rural Community Hospital Demonstration Program

Section 410A(a) of Pub. L. 108-173 requires the Secretary to establish a demonstration to test the feasibility and advisability of establishing "rural community hospitals" for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that --

! Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or treated as being so located under section 1886(d)(8)(E) of the Act;

! Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;

! Provides 24-hour emergency care services; and

! Is not designated or eligible for designation as a CAH.

Sections 410A(a)(2) and (4) of Pub. L. 108-173 specify that the Secretary is to select for participation not more than 15 rural community hospitals in rural areas of States that the Secretary identifies as having low population densities. As we indicated in the May 18, 2004 IPPS proposed rule (69 FR 28317) and corrected in the June 25, 2004 correction notice (69 FR 39521), using 2002 data from the U.S. Census Bureau, we identified 10 States with the lowest population density in which rural community hospitals must be located to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau Statistical Abstract of the United States: 2003)

Under the demonstration, participating hospitals will be paid the reasonable costs of providing covered inpatient hospital services (other than services furnished by a psychiatric or rehabilitation unit of a hospital that is a distinct part), applicable for discharges occurring in the first cost reporting period beginning on or after implementation of the demonstration program. For discharges occurring in subsequent cost reporting periods, payment is the lesser of reasonable cost or a target amount, which is the prior year's cost or, after the second cost reporting period, the prior year's target amount, adjusted by the inpatient prospective payment update factor. Covered inpatient hospital services means inpatient hospital services (defined in section 1861(b) of the Act) and includes extended care services furnished under an agreement under section 1883 of the Act.

Sections 410A(a)(5) and (a)(6) require the demonstration to be implemented not later than January 1, 2005, but not before October 1, 2004. The demonstration is to operate for 5 years. The payment change for a participating hospital under this demonstration will be implemented with the hospital's first cost reporting period beginning on or after October 1, 2004.

Section 410A of Pub. L. 108-173 requires that "in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented." Generally, when CMS implements a demonstration on a budget neutral basis, the demonstration is budget neutral in its own terms; in other words, aggregate payments to the participating

providers do not exceed the amount that would be paid to those same providers in the absence of the demonstration. This form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration participants. These reduced expenditures offset increased payments elsewhere under the demonstration, thus ensuring that the demonstration as a whole is budget neutral or yields savings. However, the small scale of this demonstration, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration could be viable under the usual form of budget neutrality. Specifically, cost-based payments to 15 small rural hospitals is likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these providers.

In order to achieve budget neutrality, as we proposed, we are adjusting national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration. We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. This is because the statutory language refers merely to ensuring that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the

demonstration . . . was not implemented," and does not identify the range across which aggregate payments must be held equal. In the May 18, 2004 proposed rule, we invited public comment on this proposal. We discuss the payment rate adjustment that would be required to ensure the budget neutrality of this demonstration in the Addendum of this final rule.

Comment: One commenter requested that the demonstration be opened to a larger number of States. The commenter stated that arbitrarily designating a number of States does not serve Medicare beneficiaries and is contrary to the intent of legislation that was proposed prior to the enactment of Pub. L. 108-173.

Response: Because Pub. L. 108-173 allows no more than 15 demonstration sites, we targeted the program in the States with the lowest population densities, consistent with the legislative language. We recognize that there are many hospitals serving people in sparsely populated rural areas in other States. Given the limitations imposed by Pub. L. 108-173, unfortunately we are unable to include many hospitals in additional States that could benefit from this provision. We have selected the demonstration areas to conform to the requirements of the law and to allow a reasonable process for determining the eligibility of applicants, given the legislative language of the statute.

Comment: One commenter stated that CMS has historically implemented demonstration projects on a budget neutral basis within the context of the given demonstration. The commenter opposed our proposal to fund the Rural Community Hospital Demonstration Program by reducing the payment rate to all hospitals paid on

the basis of DRGs, and indicated that requiring nonparticipating hospitals to fund hospitals participating in a demonstration project is a bad policy precedent.

Response: The Rural Community Hospital Demonstration Program is mandated by section 410A of Pub. L. 108-173. It is aimed at testing the feasibility and advisability of reimbursement based on reasonable cost for covered inpatient services for rural hospitals as defined by the legislation. The commenter is correct in stating that CMS usually implements demonstrations in which savings occurring among participants guarantee budget neutrality. However, we believe that the statutory authority allows us to define budget neutrality across the payment system. In short, we believe that the method that we proposed to ensure budget neutrality, which is mandated by law, is permissible under the statute.

To participate in this demonstration, a hospital must be located in one of the identified States and meet the criteria for a rural community hospital. Eligible hospitals that desire to participate in the demonstration must submit an application to CMS. Information about the demonstration and details on how to apply can be found on the CMS website: **www.cms.hhs.gov/researchers/demos/rch.asp**.

The data collection instrument for the demonstration has been approved by OMB under the title "Medicare Waiver Demonstration Application," under OMB approval number 0938-0880, with a current expiration date of July 30, 2006.

Q. Special Circumstances of Hospitals Facing High Malpractice Insurance Rate Increases

In the May 18, 2004 proposed rule (69 FR 28318), we indicated that we had received comments from several hospitals about the effects of rapidly escalating malpractice insurance premiums on hospital financial performance and continued access for Medicare beneficiaries to high quality inpatient hospital services. We are aware that malpractice insurance premiums have increased at a high rate in some areas of the country during the last few years. While we are not aware of any specific situations in which malpractice premiums have created issues of access to inpatient hospital services for Medicare beneficiaries, some hospitals have expressed concern that they may be compelled to curtail their current operations by the rate of increase in their malpractice premiums. Therefore, in the proposed rule, we invited comments on the effect of increases in malpractice insurance premiums on hospitals participating in the Medicare program, and whether increasing malpractice costs may pose access problems for Medicare beneficiaries.

Comment: Several commenters from individual hospitals and hospital associations commented on the trends in malpractice insurance premiums and the effects, or potential effects, of higher malpractice premiums on access to care. Several of these commenters provided detailed information about the specific experiences of individual hospitals or groups of hospitals.

Response: We appreciate the commenters' responses and especially the detailed information provided by several of the commenters. We will study this information

carefully as we continue to consider whether increasing malpractice costs may pose access problems for Medicare beneficiaries.

V. Changes to the PPS for Capital-Related Costs

A. Background

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services "in accordance with a PPS established by the Secretary." Under the statute, the Secretary has broad authority in establishing and implementing the PPS for hospital inpatient capital-related costs. We initially implemented the PPS for capital-related costs in the August 30, 1991 IPPS final rule (56 FR 43358), in which we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

Federal fiscal year (FY) 2001 was the last year of the 10-year transition period established to phase in the PPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital PPS payments are based solely on the Federal rate for the acute care hospitals (other than certain new hospitals and hospitals receiving certain exception payments). The basic methodology for determining capital prospective payments using the Federal rate is set forth in §412.312. For the purpose of calculating payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) x (DRG Weight) x (Geographic Adjustment Factor (GAF)) x (Large Urban Add-on, if applicable) x (COLA Adjustment for hospitals located

in Alaska and Hawaii) x (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable)

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year as specified in §412.312(c) of the existing regulations.

The regulations at §412.348(f) provide that a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. This policy was originally established for hospitals during the 10-year transition period, but as we discussed in the August 1, 2002 IPPS final rule (67 FR 50102), we revised the regulations at §412.312 to specify that payments for extraordinary circumstances are also made for cost reporting periods after the transition period (that is, cost reporting periods beginning on or after October 1, 2001).

During the transition period, under §§412.348(b) through (e), eligible hospitals could receive regular exception payments. These exception payments guaranteed a hospital a minimum payment percentage of its Medicare allowable capital-related costs depending on the class of hospital (§412.348(c)), but were available only during the 10-year transition period. After the end of the transition period, eligible hospitals can no longer receive this exception payment. However, even after the transition period, eligible hospitals receive additional payments under the special exceptions provisions at §412.348(g), which guarantees all eligible hospitals a minimum payment of 70 percent of its Medicare allowable capital-related costs provided that special exceptions payments do

not exceed 10 percent of total capital IPPS payments. Special exceptions payments may be made only for the 10 years from the cost reporting year in which the hospital completes its qualifying project, and the hospital must have completed the project no later than the hospital's cost reporting period beginning before October 1, 2001. Thus, an eligible hospital may receive special exceptions payments for up to 10 years beyond the end of the capital PPS transition period. Hospitals eligible for special exceptions payments were required to submit documentation to the intermediary indicating the completion date of their project. (For more detailed information regarding the special exceptions policy under §412.348(g), refer to the August 1, 2001 IPPS final rule (66 FR 39911 through 39914) and the August 1, 2002 IPPS final rule (67 FR 50102).)

Under the PPS for capital-related costs, §412.300(b) of the regulations defines a new hospital as a hospital that has operated (under current or previous ownership) for less than 2 years. (For more detailed information see the August 30, 1991 final rule (56 FR 43418).) During the 10-year transition period, a new hospital was exempt from the capital PPS for its first 2 years of operation and was paid 85 percent of its reasonable costs during that period. Originally, this provision was effective only through the transition period and, therefore, ended with cost reporting periods beginning in FY 2002. Because we believe that special protection to new hospitals is also appropriate even after the transition period, as discussed in the August 1, 2002 IPPS final rule (67 FR 50101), we revised the regulations at §412.304(c)(2) to provide that, for cost reporting periods beginning on or after October 1, 2002, a new hospital (defined under §412.300(b)) is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its

first 2 years of operation, unless the new hospital elects to receive fully-prospective payment based on 100 percent of the Federal rate. (Refer to the August 1, 2001 IPPS final rule (66 FR 39910) for a detailed discussion of the statutory basis for the system, the development and evolution of the system, the methodology used to determine capital-related payments to hospitals both during and after the transition period, and the policy for providing exception payments.)

B. Payments to Hospitals Located in Puerto Rico

As explained in section III.G. of this preamble, operating PPS and capital PPS payments to hospitals located in Puerto Rico are currently paid based on a blend of the Federal rate and the Puerto Rico rate. The Puerto Rico capital rate is derived from the costs of Puerto Rico hospitals only, while the capital Federal rate is derived from the costs of all acute care hospitals participating in the IPPS (including Puerto Rico). As also discussed in the section III.G. of this preamble, section 504 of Pub. L. 108-173 increases the national portion of the operating IPPS payment for Puerto Rico hospitals from 50 percent to 75 percent and decreases the Puerto Rico portion of the operating IPPS payments from 50 percent to 25 percent for discharges occurring on or after October 1, 2004. Under the broad authority of section 1886(g) of the Act, for the IPPS for capital-related costs, in the May 18, 2004 proposed rule, we proposed to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after October 1, 2004. Therefore, we proposed to revise §412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2004,

payments under the IPPS for capital-related costs to hospitals located in Puerto Rico would be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate.

We did not receive any comments on our proposal to increase the national portion of the capital IPPS payment for Puerto Rico hospitals from 50 percent to 75 percent and decrease the Puerto Rico portion of the capital IPPS payment from 50 percent to 25 percent beginning in FY 2005. Accordingly, as we proposed, we are revising §412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2004, payments under the IPPS for capital-related costs to hospitals located in Puerto Rico will be based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the capital Federal rate.

As we noted in the May 18, 2004 proposed rule, this change will increase capital IPPS payments to hospitals located in Puerto Rico because the Federal capital rate is higher than the Puerto Rico capital rate. In addition, we noted that this change is similar to the change in capital IPPS payments made to hospitals located in Puerto Rico beginning in FY 1998 that had paralleled the statutory change in the Puerto Rico blended payment amount required for operating IPPS payments to hospitals located in Puerto Rico as mandated by section 4406 of Pub. L. 105-33 (62 FR 46012 and 46048, August 29, 1997).

We did not receive any comments on our proposed blend change. Accordingly, we are adopting the proposed revision of §412.374 as final without change.

C. Exception Payment for Extraordinary Circumstances

During the transition period, hospitals were guaranteed a minimum payment of a percentage of their Medicare allowable capital-related costs, depending on the class of hospital; that is, the minimum payment level for sole community hospitals was no greater than 90 percent, for urban hospitals with at least 100 beds meeting particular disproportionate share criteria, the minimum payment level was 80 percent, and for all other hospitals, the minimum payment level was 70 percent (§§412.348(c)(i) through (iii)). Regular exception payments provided the means to ensure that hospitals received the minimum levels of capital payment. However, any amount by which a hospital's cumulative capital payments exceeded its cumulative minimum payment levels was deducted from the additional exception payment the hospital was eligible to receive (§412.348(e)). This type of exception payment ended with the end of the 10-year transition period.

In the August 1, 2002 IPPS final rule (67 FR 50102), we specified that payments to hospitals that incur capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control would be made for cost reporting periods after the transition period, that is, cost reporting periods beginning on or after October 1, 2001, as established at §412.312(e). Generally, the exception payments for extraordinary circumstances are 85 percent of Medicare's share of allowable capital-related costs attributed to the extraordinary circumstances (100 percent for sole community hospitals). This amount is offset by any amount by which a hospital's cumulative payments exceed its cumulative minimum payment levels (adjusted for the

extraordinary circumstances) under the PPS for capital-related costs. The minimum payment levels and the offsetting amounts were the same as those established for regular exceptions as indicated at §412.348(f)(4). The regulation refers to the regular exception minimum payment levels at §412.348(c)(1) and the offsetting amounts at §412.348(e)(2).

Because the regulations governing the regular exception payments, which include the minimum payment levels regulations at §412.348(c) and the offsetting amounts at §412.348(e), were effective during the transition period only, we had not previously addressed whether or not the minimum payment levels under §412.348(c) and the offsetting amounts at §412.348(e) remain applicable for extraordinary circumstances exceptions in the post-transition period. In the August 1, 2002 IPPS final rule (67 FR 50102), we clarified our policy at a new §412.312(e) that exception payments for extraordinary circumstances continued to apply to periods beginning on or after October 1, 2001. When we added §412.312(e), we did not believe it was necessary to explain in the preamble that the minimum payment levels in §412.348(c) or the offsetting amounts in §412.348(e) were incorporated into §412.312(e). However, in order to avoid any confusion, in the May 18, 2004 IPPS proposed rule, we clarified our current policy that, although the minimum payment levels established at §412.348(c)(1) are no longer in effect, they continue to be relevant in order to calculate the extraordinary circumstances exception payments after the end of the transition period. The extraordinary exception payment calculation incorporates the minimum payment levels as well as the offsetting deduction for cumulative payments. We further indicated that, although the regular exception payments themselves have expired, it has always been our policy that the

minimum payment levels will continue to be part of the formula for calculating extraordinary exception payments after the end of the transition period. In the May 18, 2004 proposed rule, we proposed to amend §412.312(e) to reflect our current policy that, for cost reporting periods beginning on or after October 1, 2001, the minimum payment levels established at §412.348(c)(1) are part of the formula for calculating extraordinary circumstances exception payments.

Similarly, in the May 18, 2004 proposed rule, we clarified our current policy that the offsetting amounts established at §412.348(e)(2) also are part of the formula for determining extraordinary circumstances exception payments after the end of the transition period, in spite of the fact that the regular exception payment provision that included the offsetting amounts at §412.348(e)(2) expired at the end of the transition period. Accordingly, we proposed to revise §412.348(e) to clarify that, for cost reporting periods beginning on or after October 1, 2001, the offsetting amounts established at §412.348(e)(2) remain in effect for extraordinary circumstances exception payments.

In addition, we also proposed to revise the period of time used to determine the offsetting amounts in §412.348(e)(2). Under existing regulations, the additional payment for extraordinary circumstances is offset by any amount by which a hospital's cumulative payments exceed its cumulative minimum payment levels under the IPPS for capital-related costs. In order to determine this offsetting amount, a hospital must keep a record of the difference between its cumulative capital payments and its cumulative minimum payment levels since it became subject to the PPS for capital-related costs. For instance, under existing regulations, if a hospital would be eligible for an additional

payment for extraordinary circumstances in FY 2005 and the hospital had been subject to the IPPS for capital-related cost since that IPPS was implemented in FY 1992, the offsetting amount would be the difference in the hospital's cumulative capital payments and its cumulative minimum payment levels for the past 13 years. Similarly, under existing regulations, if a hospital would be eligible for an additional payment for extraordinary circumstances in FY 2012 and the hospital had been subject to the capital IPPS since it was implemented in FY 1992, the offsetting amount would be the difference in the hospital's cumulative capital payments and its cumulative minimum payment levels for the past 20 years.

We believe that when the provisions for exception payments were originally implemented with the start of capital IPPS in FY 1992, it was anticipated that the offsetting amounts at §412.348(e)(2) would be determined based on a period of no longer than 10 years. However, under existing regulations, exception payments for extraordinary circumstances are offset by the difference in the hospital's cumulative payments and its cumulative minimum payment levels since it became subject to the IPPS for capital-related-costs, which for most hospitals is over 13 years. Therefore, in the May 18, 2004 proposed rule, for cost reporting periods beginning during FY 2005 and thereafter, we proposed to revise §412.312(e) to specify that the offsetting amounts in §412.348(e)(2) would be based on the hospital's capital payments and minimum payment levels from the most recent 10 years rather than from the entire period of time the hospital has been subject to the PPS for capital-related costs.

We did not receive any comments on our proposed changes to the provision for exceptions payments for extraordinary circumstances after the transition period. Accordingly, we are revising §412.312(e) to clarify the minimum payment levels and offsetting amounts that are applicable in determining exceptions payments for extraordinary circumstances after the transition period. Specifically, as proposed, we are amending §412.312(e) to specify that the minimum payment levels established at §412.348(c)(1) are part of the formula for calculating extraordinary circumstances exception payments for cost reporting periods beginning on or after October 1, 2001. In addition, as proposed, we are amending §412.348(e) to specify that the offsetting amounts established at §412.348(e)(2) remain in effect for extraordinary circumstances exception payments for cost reporting periods beginning on or after October 1, 2001. As we proposed, we are also amending §412.312(e) to specify that for cost reporting periods beginning during FY 2005 and thereafter, the offsetting amounts in §412.348(e)(2) will be based on the hospital's capital payments and minimum payment levels from the most recent 10 years rather than from the entire period of time the hospital has been subject to the PPS for capital-related costs.

Under this finalized policy, if a hospital has been paid under the IPPS for capital-related costs for less than 10 years, the offsetting amounts will be based on the hospital's capital payments and minimum payment levels beginning with the date the hospital became subject to the PPS for capital-related costs. For example, if a hospital is eligible for an additional payment for extraordinary circumstances in FY 2005 and the hospital had been subject to the IPPS for capital-related costs since FY 1992 (13 years),

the offsetting amounts used in the calculation of the extraordinary circumstances exception payment will be based on the hospital's cumulative capital PPS payments and cumulative minimum payment levels for the hospital's cost reporting period beginning during FY 1995 through FY 2004. Similarly, if a hospital is eligible for an additional payment for extraordinary circumstances in FY 2005 and the hospital had only been subject to the PPS for capital-related costs since FY 2000 (5 years), the offsetting amounts used in the calculation of the extraordinary circumstances exception payment will be based on the hospital's cumulative capital IPPS payments and cumulative minimum payment levels for the hospital's cost reporting periods beginning during FY 2000 through FY 2004

D. Treatment of Hospitals Previously Reclassified for the Operating IPPS Standardized Amounts

As we discussed in section IV.C. of this preamble, prior to April 1, 2003, the standardized amounts varied under the operating IPPS based on a hospital's geographic location (large urban versus other urban and rural areas). Furthermore, previously, a hospital could be reclassified to a large urban area by the MGCRB for the purpose of the standardized amount if certain criteria were met (as described in Part 412, Subpart L of the Medicare regulations).

Similarly, the standard capital Federal rate under the PPS for capital-related costs is adjusted to reflect the higher costs incurred by hospitals located in large urban areas (large urban add-on at §412.316), as well as for hospitals in urban areas with at least 100 beds serving low-income patients (capital disproportionate share (DSH) adjustment

at §412.320). In the past, if a rural or other urban hospital was reclassified to a large urban area for purposes of the operating IPPS standardized amount under §412.63, the hospital also was then eligible for a large urban add-on payment, as well as a DSH payment, under the IPPS for capital-related costs.

Section 402(b) of the Consolidated Appropriations Resolution, 2003, Pub. L. 108-7, and section 402 of Pub. L. 108-89, (a Welfare Reform Act), provide that, for discharges occurring on or after April 1, 2003 and before March 31, 2004, under the operating IPPS, all hospitals are paid based on the large urban standardized amount, regardless of geographic location or MGCRB redesignation. Section 401(a) of Pub. L. 108-173 amended section 1886(d)(5)(A)(iv) by adding a subsection (II) that permanently equalizes the standardized amounts for large urban areas and for other urban and rural areas for discharges occurring on or after April 1, 2004.

In addition, under section 1886(d) of the Act, a hospital may reclassify under the operating IPPS only for the purpose of either its standardized amount or its wage index adjustment, or both. As further specified in regulations at §412.230, a hospital may be reclassified for purposes of the standardized amount only if the area to which the hospital seeks redesignation has a higher standardized amount than the hospital currently receives. Because there are no longer differences in standardized amounts due to geographic classification as a result of the section 401 amendment, hospitals are no longer eligible to reclassify solely for standardized amount purposes. Accordingly, as discussed in the May 18, 2004 proposed rule, the MGCRB denied all FY 2005 standardized amount reclassification requests. We note that although Pub. L. 108-7 and Pub. L. 108-89 also

equalized the standardized amounts for all hospitals in FY 2004, because these laws were not enacted until after the MGCRB had already made its reclassification determinations for FY 2004, eligible hospitals received reclassification approval for the purposes of the standardized amount for FY 2004. However, in this case, Pub. L. 108-173 was enacted before the MGCRB issued its reclassification decisions for FY 2005. Therefore, we did not propose that any hospital would be reclassified for the purpose of the standardized amounts in FY 2005.

As we explained in the May 18, 2004 proposed rule, the changes to the operating IPPS described above have an effect on payments under the IPPS for capital-related costs. Rural and other urban hospitals that were previously eligible to receive the large urban add-on and DSH payments under the IPPS for capital-related costs if they reclassified to a large urban area for the purpose of the standardized amount under the operating IPPS, will no longer be reclassified, and therefore, will not be eligible to receive those additional payments under the IPPS for capital-related costs.

Our analysis indicates that rural and other urban hospitals will gain approximately $0.5 billion in FY 2005 in operating IPPS payments due to the equalization of the standardized amounts compared to a relatively small adjustment to payments for capital-related costs under the IPPS. We understand that Congress was aware of the effect of the equalization of the standardized amounts on the rural and other urban hospitals' adjustments under the IPPS for capital-related costs. This approach is consistent with section 4203 of the BBA, which prevented hospitals from reclassifying to a different area to get an additional payment solely for DSH purposes under the operating

IPPS. The restriction at section 4203 clearly indicates Congress' intent to maintain the principle that reclassifications under section 1886(d) of the Act are only intended to be made for purposes of either the standardized amount or the wage index adjustment.

Therefore, in the May 18, 2004 proposed rule, we clarified that, beginning in FY 2005, only hospitals geographically located in a large urban area (as defined in proposed revised §412.63(c)(6)) would be eligible for large urban add-on payments under the PPS for capital-related costs under §412.312(b)(2)(ii) and §412.316(b). We proposed that, beginning in FY 2005, only hospitals serving low-income patients that are geographically located in an urban area (as defined in proposed new §412.64 and discussed in section IV.D. of this preamble) with 100 or more beds (or that meet the criteria in §412.106(c)(2)) would be eligible for DSH payments under the PPS for capital-related costs under §412.320.

We did not received any comments on the effect of the equalization of the operating IPPS standardized amounts on payments under the PPS for capital-related costs. Therefore, as we proposed, beginning in FY 2005 and thereafter, only hospitals geographically located in a large urban area (as defined in revised §412.63(c)(6)) will be eligible for large urban add-on payments under the PPS for capital-related costs under §412.312(b)(2)(ii) and §412.316(b). Similarly, as we proposed, beginning in FY 2005 and thereafter, only hospitals serving low-income patients that are geographically located in an urban area (as defined in new §412.64 and discussed in section IV.D. of this preamble) with 100 or more beds (or that meet the criteria in §412.106(c)(2)) will be eligible for DSH payments under the PPS for capital-related costs under §412.320.

E. Geographic Classification and Definition of Large Urban Area

1. Core-Based Statistical Areas

As we discuss in greater detail in section III.B. of this preamble, we are adopting changes to the MSA criteria used to define hospital labor market areas based on the new Core-Based Statistical Areas (CBSA) definitions announced by OMB on June 6, 2003, which are based on 2000 Census data. We currently define hospital labor market areas based on the definitions of Metropolitan Statistical Areas (MSAs), Primary MSAs (PMSAs), and New England County Metropolitan Areas (NECMAs) under standards issued by OMB in 1990. In addition, OMB designates Consolidated MSAs (CMSAs). A CMSA is a metropolitan area with a population of one million or more, comprised of two or more PMSAs (identified by their separate economic and social character). Under the operating PPS, the wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. For purposes of the hospital wage index, we use the PMSAs rather than CMSAs because they allow a more precise breakdown of labor costs. However, if a metropolitan area is not designated as part of a PMSA, we use the applicable MSA.

As we discuss in sections III.B.3. and IV.C. of this preamble, in the May 18, 2004 proposed rule, we proposed to adopt OMB's new CBSA designations to define labor market areas for discharges occurring on or after October 1, 2004, which would be set forth in regulations under a proposed new §412.64. Currently, the large urban location adjustment under §412.316(b) and the DSH adjustment for certain urban hospitals under §412.320 for payments for capital-related costs rely on the existing geographic

classifications set forth at §412.63. Because we proposed to adopt OMB's new CBSA designations for FY 2005 and thereafter, under proposed new §412.64, we proposed to revise §412.316(b) and §412.320(a)(1) to specify that, for discharges on or after October 1, 2004, the payment adjustments under these sections, respectively, would be based on the geographic classifications at proposed new §412.64.

Comment: One commenter expressed concern that the implementation of the new MSA definitions (proposed §412.64) will result in some hospitals losing the 3-percent large urban add-on payment adjustment provided for at §412.316(b) that they previously qualified for under the current MSA definitions (at existing §412.63). The commenter recommended that we grandfather the large urban add-on payment adjustment for the affected hospitals or, alternatively, maintain the add-on for the affected hospitals for 5 years.

Response: The commenter is correct that as a result of the implementation of the new MSA definitions, hospitals that had previously been located in a large urban area under the current MSA definitions, but will now be located in another urban or rural area under the new MSA definitions will no longer qualify for certain payment adjustments that they previously qualified for under the prior MSA definitions, including the 3-percent large urban add-on payment adjustment at §412.312(b)(2)(ii) and §412.316(b). As discussed previously, in the May 18, 2004 proposed rule, we solicited comments on the effect of the equalization of the operating IPPS standardized amount. Specifically, we discussed that rural and other urban hospitals that were previously eligible to receive the large urban add-on payment adjustment (and DSH payment adjustment) under the

IPPS for capital-related costs if they reclassified to a large urban area for the purpose of the standardized amount under the operating IPPS, will no longer be reclassified and, therefore, will not be eligible to receive those additional payments under the IPPS for capital-related costs beginning in FY 2005. As we noted previously, we received no comments on that clarification.

One of the results of the decennial census is that changes in population data may affect a hospital's geographic classification under OMB's standards. We explain in further detail in section III.B. of this preamble the reason for adopting OMB's revised definitions for geographical statistical areas. The OMB announced the new MSAs based on Census 2000 data over a year ago (a copy of the June 6, 2003 announcement may be obtained at the following Internet address: http://www.whitehouse.gov/omb/bulletins/fy04/b04-03.html). Although OMB's revised definitions were available early last summer, we did not propose to adopt the changes until FY 2005 so that we could thoroughly assess the impact of adopting these revised geographical criteria.

In section III.B.3.d.of the preamble, we also discuss the establishment of a transition period for the wage index to help mitigate the change from the current MSAs to the new MSAs based on the OMB's revised CBSA definitions. However, as we note below in section III. of the Addendum to this final rule, total payments to hospitals under the IPPS are relatively unaffected by changes in the capital PPS payments since capital IPPS payments constitute about 10 percent of hospital's total (operating and capital) PPS payments and in addition, the changes we proposed are only a small percentage of total

capital IPPS payments. The large urban add-on payment adjustment under section §412.312(b)(2)(ii) and §412.316(b) provides for an additional payment equal to 3 percent of the amount otherwise payable to the hospital based on the capital Federal rate. Because the large urban add-on payment adjustment is a very small percentage of a hospital's total IPPS payments, we do no estimate a "significant payment implication" to those hospitals that will no longer be eligible for the large urban add-on payment adjustment under the new MSA definitions. Therefore, we do not believe that it is necessary to grandfather or maintain the large urban add-on for the hospitals that previously qualified for that adjustment under the current MSA definitions. As previously discussed, we proposed and adopted as final our policy that, beginning in FY 2005 and thereafter, only those hospitals geographically located in a large urban area (as defined in revised §412.63(c)(6)) will be eligible for the large urban add-on payment adjustment provided under §412.312(b)(2)(ii) and §412.316(b). Similarly, beginning in FY 2005 and thereafter, to receive capital IPPS DSH payments under §412.320, a hospital will need to be geographically located in an urban area (as defined in new §412.64) and meet all other requirements of §412.320. Accordingly, we are adopting our proposed revisions as final without change.

2. Metropolitan Divisions

Under the revised MSA criteria based on CBSAs, a Metropolitan Division is a county or group of counties located within an MSA with a core population of at least 2.5 million, representing an employment center, plus adjacent counties associated with the main county or counties through commuting ties (see section III.B.3.b. of this

preamble for further details). In the May 18, 2004 proposed rule, to conform to the proposed changes to the MSA criteria discussed in section III.B. of this preamble, we proposed to use the Metropolitan Divisions where applicable under the CBSA definitions. Thus, similar to our treatment of PMSAs as labor market areas where applicable, we proposed to use the Metropolitan Divisions rather than MSAs to define labor market areas.

Currently, under the existing MSA criteria, a large urban area is defined at existing §412.63(c)(6) as an MSA with a population of more than 1,000,000 or a NECMA with a population of more than 970,000 based on the most recent available population data published by the Bureau of the Census. As noted above, we currently use the PMSAs rather than CMSAs to define labor market areas. Accordingly, we currently determine large urban areas under existing §412.63(c)(6) based on the most recent available population data for each PMSA rather than the CMSA. Similarly, because we proposed to treat Metropolitan Divisions of MSAs as labor market areas under the proposed changes based on CBSA designations, we proposed to designate large urban areas based on the most recent available population data for each Metropolitan Division, rather than the MSA.

As discussed in section III.B.3.b. of the proposed rule and this final rule under the CBSA definitions, there are 11 MSAs containing Metropolitan Divisions: Boston; Chicago; Dallas; Detroit; Los Angeles; Miami; New York; Philadelphia; San Francisco; Seattle; and Washington, D.C. Within these 11 areas are a total of 29 Metropolitan Divisions, which would be treated as MSAs. Of those 29 MSAs, 23 meet the definition

of large urban area under §412.63(c)(6) (as denoted in Tables 4A and 4B in the Addendum to this final rule). Under the proposed and final changes to the MSA criteria, there are a total of 62 large urban areas, including those 23 Metropolitan Divisions, as denoted in Tables 4A and 4B in the Addendum to this final rule.

In the May 18, 2004 proposed rule, we proposed to clarify that the current definition of large urban area at existing §412.63(c)(6) would remain in effect for the purpose of the large urban add-on adjustment to the Federal rate under the PPS for capital-related costs under §§412.312(b)(2)(ii) and 412.316(b). With the equalization of the operating standardized amounts (as discussed in section IV.D. of this preamble), we proposed to revise the regulations under §412.63(c), and make them effective for FYs 1984 through 2004, and to add a new §412.64 that would be applicable for FYs 2005 and thereafter. We indicated that because we would compute a single standardized amount for hospitals located in all areas beginning in FY 2005, the term "large urban area" is no longer applicable under the operating PPS and therefore, a definition of large urban area would not be included under the proposed new §412.64. However, the term "large urban area" continues to be applicable under the capital IPPS for the large urban add-on adjustment at §§412.312(b)(2)(ii) and 412.316(b). Therefore, we proposed to revise §§412.312(b)(2)(ii) and 412.316(b) to state that the definition of large urban area set forth at §412.63(c)(6) would continue to be in effect under the capital PPS for discharges occurring on or after October 1, 2004. In addition, since under the new definitions, NECMAs no longer exist, we clarify as an interpretive matter that the reference in §412.63(c)(6) to NECMAs will be interpreted as referring to New England MSAs.

We did not receive any comments on our proposed clarification that the current definition of large urban area at existing §412.63(c)(6) would remain in effect for the purpose of the large urban add-on adjustment to the capital IPPS Federal rate under §§412.312(b)(2)(ii) and 412.316(b). Accordingly, as we proposed, we are revising §§412.312(b)(2)(ii) and 412.316(b) to state that the definition of large urban area set forth at §412.63(c)(6) will continue to be in effect under the capital IPPS for discharges occurring on or after October 1, 2004.

VI. Changes for Hospitals and Hospital Units Excluded from the IPPS

A. Payments to Excluded Hospitals and Hospital Units (§§413.40(c), (d), and (f))

1. Payments to Existing Excluded Hospitals and Hospital Units

Section 1886(b)(3)(H) of the Act (as amended by section 4414 of Pub. L. 105-33) established caps on the target amounts for certain existing hospitals and hospital units excluded from the IPPS for cost reporting periods beginning on or after October 1, 1997 through September 30, 2002. For this period, the caps on the target amounts (as defined at §413.40(c)(4)(iii)(B)) applied to the following three classes of excluded hospitals or units: psychiatric hospitals and units, rehabilitation hospitals and units, and LTCHs. In accordance with section 1886(b)(3)(H)(i) of the Act and effective for cost reporting periods beginning on or after October 1, 2002, payments to these classes of existing excluded hospitals or hospital units are no longer subject to caps on the target amounts.

In accordance with existing §§413.40(c)(4)(ii) and (d)(1)(i) and (ii), where applicable, excluded psychiatric hospitals and units continue to be paid on a reasonable cost basis, and payments are based on their Medicare inpatient operating costs, not to

exceed the ceiling, up to the date that an inpatient psychiatric facility PPS discussed in section VII.A. of this preamble becomes effective. The ceiling is computed using the hospital's or unit's target amount from the previous cost reporting period, updated by the rate-of-increase specified in §413.40(c)(3)(viii) of the regulations, and then multiplying this figure by the number of Medicare discharges.

Effective for cost reporting periods beginning on or after October 1, 2002, rehabilitation hospitals and units are paid in accordance with the IRF PPS at 100 percent of the Federal rate. In addition, effective for cost reporting periods beginning on or after October 1, 2002, LTCHs are no longer paid on a reasonable cost basis, but are paid under a DRG-based PPS. However, as part of the PPS for LTCHs, we established a 5-year transition period from reasonable cost-based reimbursement to a fully Federal PPS. Under the LTCH PPS, a LTCH that is subject to the blend methodology may elect to be paid 100 percent of the Federal prospective rate. We have proposed, but not finalized, an inpatient psychiatric facility (IPF) prospective payment system under which psychiatric hospitals and psychiatric units would no longer be paid on a reasonable cost basis but would be paid on a prospective per diem basis. (Sections VI.A.3, 4, and 5 of this preamble contain a more detailed discussion of the IRF PPS, the LTCH PPS and the proposed IPF PPS.)

2. Updated Caps for New Excluded Hospitals and Units

Section 1886(b)(7) of the Act established a payment limitation for new psychiatric hospitals and units, rehabilitation hospitals and units, and long-term care hospitals that first receive payment as a hospital or unit excluded from the IPPS on or

after October 1, 1997. A discussion of how the payment limitation was calculated can be found in the August 29, 1997 final rule with comment period (62 FR 46019); the May 12, 1998 final rule (63 FR 26344); the July 31, 1998 final rule (63 FR 41000); and the July 30, 1999 final rule (64 FR 41529).

The amount of payment for a "new" psychiatric hospital or unit (as defined at 42 CFR 413.40(f)(2)(ii) will be determined as follows:

- Under existing §413.40(f)(2)(ii), for the first two 12-month cost reporting periods, the amount of payment is the lesser of: (1) the operating costs per case; or (2) 110 percent of the national median (as estimated by the Secretary) of the target amounts for the same class of hospital or unit for cost reporting periods ending during FY 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital or unit first receives payments under section 1886 of the Act, as adjusted for differences in area wage levels. The amount of payment, as determined above, is also referred to as a payment limitation or target amount since the payment for the first 2 years of a hospital or unit cannot exceed the amount determined under §413.40(f)(2)(ii).

- Under existing §413.40(c)(4)(v), for cost reporting periods following the hospital's or unit's first two 12-month cost reporting periods, the target amount is equal to the amount determined under §413.40(f)(2)(ii) for the preceding cost reporting period, updated by the applicable hospital market basket increase percentage to the third cost reporting period.

The amounts included in the following table are the payment amounts (or payment limitations) reflecting the updated 110 percent of the national median target amounts of new excluded psychiatric hospitals and units. The payment amount is for cost reporting periods beginning during FY 2005. These figures have been updated with the most recent data available to reflect the projected market basket increase percentage of 3.3 percent. This projected percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient hospital services (as projected by the Office of the Actuary of CMS based on its historical experience with the IPPS). For a new provider, the labor-related share of the target amount is multiplied by the appropriate geographic area wage index, without regard to IPPS reclassifications, and added to the nonlabor-related share in order to determine the per case payment limitation on payment under the statutory payment methodology for new providers (section 1886(b)(7)(A)(i) of the Act and §413.40(f)(2)(ii) of the regulations).

Class of Excluded Hospital or Unit	FY 2005 Labor-Related Share	FY 2005 Nonlabor-Related Share
Psychiatric	$7,535	$2,995

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation was no longer applicable to new LTCHs as defined under §412.23(e)(4), since LTCHs with a first cost reporting period beginning on or after October 1, 2002, are paid 100 percent of the Federal rate for LTCH PPS. However, new LTCHs, as defined under §413.40(f)(2)(ii), which were paid as LTCHs before the

effective date of the LTCH PPS, were eligible for a blended payment for up to 5 years under the LTCH PPS for cost reporting periods beginning on or after October 1, 2002. Those hospitals would have had their payments determined using the payment limitation for use in determining the TEFRA portion of this blend. However, an update of this payment limitation is no longer necessary after FY 2002 because the same payment limitation published for FY 2002 was effective for 2 years for "new" LTCHs as defined under §413.40(f)(2)(ii), including those "new" LTCHs with a first cost reporting period beginning in FY 2002. A target amount would be determined for any subsequent years that those "new" LTCHs were eligible for a blended payment under the LTCH PPS. Thereafter, the LTCH is paid under the LTCH PPS. Accordingly, since a new hospital established on or after October 1, 2002 is no longer subject to this payment limitation and any new hospital as defined at §413.40(f)(2)(ii) would also not have its FY 2002 payment limitation for new LTCHs as defined under §413.40(f)(2)(ii).

A freestanding inpatient rehabilitation hospital, an inpatient rehabilitation unit of an acute care hospital, and an inpatient rehabilitation unit of a CAH are collectively referred to as an IRF.

Effective for cost reporting periods beginning on or after October 1, 2002, this payment limitation is also no longer applicable to new rehabilitation hospitals and units because they are paid 100 percent of the Federal prospective rate under the IRF PPS. Therefore, it is also no longer necessary to update the payment limitation for new rehabilitation hospitals or units.

3. Implementation of a PPS for IRFs

Section 1886(j) of the Act, as added by section 4421(a) of Pub. L. 105-33, provided for the phase-in of a case-mix adjusted PPS for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation hospital unit (referred to in the statute as rehabilitation facilities) for cost reporting periods beginning on or after October 1, 2000, and before October 1, 2002, with a fully implemented PPS for cost reporting periods beginning on or after October 1, 2002. Section 1886(j) of the Act was amended by section 125 of Pub. L. 106-113 to require the Secretary to use a discharge as the payment unit under the PPS for inpatient hospital services furnished by rehabilitation facilities and to establish classes of patient discharges by functional-related groups. Section 305 of Pub. L. 106-554 further amended section 1886(j) of the Act to allow rehabilitation facilities, subject to the blend methodology, to elect to be paid the full Federal prospective payment rather than the transitional period payments specified in the Act.

On August 7, 2001, we issued a final rule in the **Federal Register** (66 FR 41316) establishing the PPS for inpatient rehabilitation facilities, effective for cost reporting periods beginning on or after January 1, 2002. There was a transition period for cost reporting periods beginning on or after January 1, 2002 and ending before October 1, 2002. For cost reporting periods beginning on or after October 1, 2002, payments are based entirely on the Federal prospective payment rate determined under the IRF PPS.

4. Implementation of a PPS for LTCHs

In accordance with the requirements of section 123 of Pub. L. 106-113, as modified by section 307(b) of Pub. L. 106-554, we established a per discharge, DRG-based PPS for LTCHs as described in section 1886(d)(1)(B)(iv) of the Act for cost reporting periods beginning on or after October 1, 2002, in a final rule issued on August 30, 2002 (67 FR 55954). The LTCH PPS uses information from LTCH hospital patient records to classify patients into distinct LTC-DRGs based on clinical characteristics and expected resource needs. Separate payments are calculated for each LTC-DRG with additional adjustments applied.

We published in the **Federal Register** on May 7, 2004, a final rule (69 FR 25673) that updated the payment rates for the LTCH PPS and made policy changes effective for a new LTCH PPS rate year of July l, 2004, through June 30, 2005. The 5-year transition period from reasonable cost-based reimbursement to the fully Federal prospective rate will end with cost reporting periods beginning on or after October 1, 2005 and before October 1, 2006.

5. Development of a PPS for IPFs

Section 124 of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) requires the development of a per diem prospective payment system (PPS) for payment of inpatient hospital services furnished in psychiatric hospitals and psychiatric units of acute care hospitals (inpatient psychiatric facilities (IPFs)). We published a proposed rule to implement the IPF PPS on November 28, 2003 (68 FR 66920). We published a proposed rule to implement the IPF PPS on November 28, 2003 (68 FR 66920). On January 30, 2004, we published a notice to

extend the comment period for 30 additional days (69 FR 4464). The comment period closed on March 26, 2004.

Under the proposed rule, we would compute a Federal per diem base rate to be paid to all IPFs based on the sum of the average routine operating, ancillary, and capital costs for each patient day of psychiatric care in an IPF adjusted for budget neutraility. The Federal per diem base rate would be adjusted to reflect certain characteristics such as age, specified DRGs, and selected high-cost comorbidities, and certain facility characteristics such as wage index adjustment, rural location, and indirect teaching costs.

The November 28, 2003 proposed rule assumed an April 1, 2004 effective date for the purpose of ratesetting and calculating impacts. However, we are still in the process of analyzing public comments and developing a final rule for publication. The effective date of the IPF PPS would occur 5 months following publication of the final rule.

6. Technical Changes and Corrections

a. Change Related to Establishment of Payments for Excluded Hospitals

We have become aware of a number of technical errors in the existing regulations governing how we determine payments to hospitals that are excluded from the IPPS. The existing regulations under §413.40 set forth requirements for establishing the ceiling on the rate of increase in operating costs per case for hospital inpatient services furnished to Medicare beneficiaries that will be recognized as reasonable for purposes of determining the amount of Medicare payments. The rate-of-increase ceiling applicable to cost reporting periods has been adjusted a number of times since it was first applied for

hospital cost reporting periods beginning on or after October 1, 1982. In revising the regulations over the years to reflect the different applicable adjustments for cost reporting periods for specific providers, we have inadvertently overlooked updating or conforming §413.40 to reflect various statutory changes. We note that, although we erroneously omitted the technical changes in the regulation text, we did, in fact, comply with the changes required by the statute when determining the rate-of-increase ceiling. Therefore, in the May 18, 2004 proposed rule (69 FR 28323), we proposed to make several changes to §413.40(c)(4)(iii) in order to conform it to section 1886(b)(3)(J) of the Act. These changes are as follows: (1) in §413.40(c)(4)(iii)(A)(1) and (c)(4)(iii)(B)(4)(i), the phrase "on or after October 1, 2001", should read "during FY 2001"; and in §413.40(c)(4)(iii)(A)(2), the phrase “on or after October 1, 2000" should read "during FY 2001". In order to include pertinent changes that were erroneously omitted from the regulatory text and to conform the text to section 1886(b)(2)(A) of the Act, we proposed to delete the phrase "and ending before October 1, 2000" in §413.40(d)(4)(i) because, in section 1886(b)(2)(A) of the Act, there is no ending date for the continuous improvement bonus payment. In addition, at §413.40(d)(4)(ii), we proposed to delete the word "ending" from the introductory phrase so that the phrase would read, "For cost reporting periods beginning on or after October 1, 2000 and before September 30, 2001." The word “ending” in the existing language at best limits the provision to cost reporting periods beginning on October 1, 2000. The provision was intended to apply to cost reporting periods beginning during all of FY 2001.

We did not receive any public comments on this proposal and, therefore, are adopting it as final without modification.

b. Technical Correction Related to Long-Term Care Hospitals

In the June 6, 2003 **Federal Register** (68 FR 3§4122), we published a final rule establishing the annual update of the payment rates for the Medicare prospective payment system for inpatient hospital services provided by LTCHs. In that final rule, we added a new paragraph (h)(6) to §§412.22. This paragraph eliminated the bed size limitation for pre-1997 LTCHs with satellite facilities once the LTCH is paid at 100 percent of the Federal rate.

In the August 1, 2003 **Federal Register** (68 FR 45674)**,** we published a final rule that established the annual update for payment rates for the Medicare prospective payment system for inpatient hospital services provided by IRFs. The IRF PPS final rule added a new paragraph (h)(7) to §§412.22. Through an inadvertent error, in the August 1, 2003 IRF PPS final rule, we removed and reserved §§412.22(h)(6) that was added by the June 6, 2003 LTCH PPS final rule. Therefore, we are correcting this error by adding a new paragraph §§412.22(h)(6) to reinstate the regulatory language from the June 6, 2003 LTCH PPS final rule.

7. Report of Adjustment (Exception) Payments

Section 4419(b) of Pub. L. 105-33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment (exception) payments made to excluded hospitals and units, by reason of section 1886(b)(4) of the Act, during the previous fiscal year.

The process of requesting, adjudicating, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, an excluded hospital or unit must file its cost report for a fiscal year with its intermediary within 5 months after the close of its cost reporting period. The fiscal intermediary then reviews the cost report and issues a Notice of Program Reimbursement (NPR) within approximately 2 months after the filing of the cost report. If the hospital's operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment within 6 months from the date of the NPR. The intermediary, or CMS, depending on the type of adjustment requested, then reviews the request and determines if an adjustment payment is warranted. This determination is often not made until more than 6 months after the date the request is filed. Therefore, it is not possible to provide data in this final rule. However, in an attempt to provide interested parties with data on the most recent adjustments for which we do have data, we are publishing data on adjustments that were processed by the fiscal intermediary or CMS during FY 2003.

The table below includes the most recent data available from the fiscal intermediaries and CMS on adjustment payments that were adjudicated during FY 2003. As indicated above, the adjustments made during FY 2003 only pertain to cost reporting periods ending in years prior to FY 2002. Total adjustment payments awarded to excluded hospitals and units during FY 2003 are $11,931.305. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating cost over ceiling, and the amount of the adjustment payment.

Class of Hospital	Number	Excess cost over ceiling	Adjustment payments
Rehabilitation	15	$10,020,001	$4,320,038

Psychiatric	18	9,853,039	5,233,873
Long-Term Care	1	2,052,853	1,545,245
Children's	--	--	--
Cancer	1	9,014,031	832,149
Christian Science	--	--	--

B. Criteria for Classification of Hospitals-Within-Hospitals

Existing regulations at §412.22(e) define a hospital-within-a-hospital as a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital. Moreover, existing §412.22(f) provides for the grandfathering of hospitals-within-hospitals that were in existence on or before September 30, 1995.

One of the goals of our hospital-within-hospital regulations at §412.22(e) has been to prevent a LTCH co-located with an acute care hospital to function as a unit of that hospital, a situation precluded under section 1886(d)(1)(B) of the Act. This policy protects the integrity of the IPPS by ensuring that costly, long-stay patients who could reasonably continue treatment in that setting would not be unnecessarily discharged to an onsite LTCH, a behavior that would skew and undermine the Medicare IPPS DRG system. Further, there is concern that the hospital-within-hospital configuration could result in patient admission, treatment, and discharge patterns that are guided more by attempts to maximize Medicare payments than by patient welfare. We believe that the unregulated linking of an IPPS hospital and a hospital excluded from the IPPS could lead to two Medicare payments for what was essentially one episode of patient care.

In the September 1, 1994 IPPS final rule (59 FR 45389), we first discussed hospitals-within-hospitals, describing them as entities that were manipulating the

conditions of participation (COPs) for hospitals under Medicare, set forth in regulations at 42 CFR Part 482, to permit them to receive exclusion from the prospective payment systems. Specifically, these hospitals have begun to organize what they themselves refer to as the 'hospital-within-a-hospital' model. Under this model, an entity may operate in space leased from a hospital, and have most or all services furnished under arrangements by employees of the lessor hospital. The newly organized entity may be operated by a corporation formed and controlled by the lessor hospital, or by a third entity that controls both. In either case, the new entity seeks State licensure and Medicare participation as a hospital, demonstrates that it has an average length of stay of over 25 days, and obtains an exclusion from the IPPS. The effect of this process is to extend the long-term care hospital exclusion to what is, for all practical purposes, a "long-term care unit." We noted that the averaging concept that underlies the IPPS recognizes that some patients will stay longer and consume more resources than expected, while others will have shorter, less costly stays. We envisioned that abuse of the PPSs could result if an acute care hospital under the IPPS "diverted all long-stay cases to the excluded unit, leaving only shorter, less costly cases to be paid for under the IPPS. In such cases, hospitals would profit inappropriately from prospective payments." Further, we stated that we believed that the "exclusion of long-term care 'units' was inconsistent with the statutory scheme." Section 1886(d)(1)(B) of the Act clearly provides for an exclusion of LTCHs from the acute care IPPS. While the statute also provides for an exclusion for psychiatric units and rehabilitation units, it does not provide for an exclusion of long-term care units. (59 FR 45389)

In addition, in that September 1, 1994 final rule, we proceeded to establish "separateness and control" regulations at (then) §412.23(e) that required the two hospitals to have separate medical and administrative governance and decision-making and also ensured that each hospital operated as a separate facility. We believed at that time that such rules were sufficient solutions to our concerns about these new entities and, therefore, we did not preclude common ownership of the host and the LTCH at that time.

In the ensuing decade, we have revisited the issue of hospitals-within-hospitals several times (for example, 60 FR 45836, September 1, 1995; 62 FR 46012, August 29, 1997; 67 FR 56010, August 30, 2002; 68-7 FR 45462, August 1, 2003) during which we clarified and amplified the separateness and control requirements. In the August 29, 1997 IPPS final rule, we extended the application of these rules beyond LTCHs to include other classes of facilities that might seek exclusion from the IPPS as hospitals-within-hospitals, such as IRFs. In addition, in the August 29, 1997 final rule, we also established a "grandfathering" provision for hospitals-within-hospitals in existence prior to September 30, 1995, at §412.22(f), and in the August 1, 2003 IPPS final rule, we clarified and codified the requirements for "grandfathered" hospitals-within-hospitals (68 FR 45463).

As stated earlier, presently, a hospital-within-a-hospital must meet the separateness and control criteria set forth at §412.22(e). In order to be excluded from the IPPS, the hospital-within-a-hospital must have a separate governing body, a separate chief medical officer, a separate medical staff, and a separate chief executive officer. Regarding the performance of basic hospital functions (§412.22(e)(5)), currently, the

hospital must meet at least one of the following criteria: (i) the hospital performs the basic functions through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals; (ii) for the same period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in §412.2(c) (that is, inpatient operating costs include operating costs for routine services, such as costs of room, board, and routine nursing services; operating costs for ancillary services such as laboratory or radiology; special care unit operating costs; malpractice insurance costs related to serving inpatients; and preadmission services); or (iii) for the same period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the hospital from a source other than another hospital occupying space in the same building or on the same campus or with a third entity that controls both hospitals.

It is our experience that the vast majority of hospitals-within-hospitals have elected to meet the second of the three criteria at §412.22(e)(5), that is, the cost of the services that the hospital obtained from the co-located hospital or with a third entity that controls both hospitals is no more than 15 percent of its total inpatient operating costs. In establishing the 15-percent rule, we originally believed that we would be able to detect a

true corporate identity and actual function and to guard against an arrangement that could undermine the statutory preclusion of long-term care units. We sought to distinguish admissions to independently operating facilities from what were, in effect, transfers of patients from one unit of the corporation to another unit of the corporation without a truly distinct and separate corporate identity. Our underlying policy rationale was that, if an entity could not be separately identified, it effectively would be functioning as a mere unit of the parent entity in violation of the statutory prohibition on long-term care units. We explained in the September 1, 1994 rule (59 FR 45390) that "if an entity is effectively part of another hospital and the principles of the prospective payment system do apply well to the organization as a whole, then it would not be appropriate to exclude part of that organization from the prospective payment system."

Although we have periodically revisited the phenomenon of hospitals-within-hospitals in our rules and we have revised or clarified some related issues, we have not proposed significant changes in our policies in this area for some time. This is despite the significant changes that have been made in the payment systems for Medicare-certified, excluded hospitals and units. Medicare payments to two types of IPPS-excluded hospitals, LTCHs and IRFs, are now made on a prospective basis. We believe that, in part, the new LTCH PPS is one of the reasons for the rapidly increasing number of LTCH hospitals-within-hospitals. In its June 2003 Report to the Congress, MedPAC identified hospitals-within-hospitals as the fastest growing type of LTCHs, and specified that the number had grown from 10 in 1993 to 114 in 2002, an average annual increase of approximately 30 percent (p. 85). In the August 30, 2002 final rule that

implemented the PPS for LTCHs, we noted that ". . .we remain extremely concerned about rapid growth in LTCH hospitals-within-hospitals and will be collecting data on the relationship among host hospitals, hospitals-within-hospitals, and parent corporations in order to determine the need for additional regulation" (67 FR 56010). We indicated that if, as a consequence of these monitoring activities, we determine the need to revisit existing regulations dealing with ownership and control of hospitals-within-hospitals, we would follow the notice and comment rulemaking process (67 FR 56011).

The LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002. We have gathered considerable anecdotal information from inquiries from the provider community, fiscal intermediaries, and, particularly, from the survey and certification divisions of our CMS Regional Offices.

As we had indicated in the May 18, 2004 proposed rule (69 FR 28323 through 28327), we believe that existing policies regarding hospitals-within-hospitals do not sufficiently protect the Medicare program from the problems that we envisioned in the September 1, 1994 final rule. We also questioned the effectiveness of the "separateness and control" requirements alone because entities have used complex arrangements among corporate affiliates, and obtained services from those affiliates, thereby impairing or diluting the separateness of the corporate entity. While technically remaining within the parameters of the rule, these arrangements have intermingled corporate interests so that the corporate distinctness has been lost.

In corporate law, several standards are used to determine how much separateness is sufficient for corporate autonomy to be recognized. The courts have applied a number

of tests and considered a number of factors in determining when a parent corporation is liable for the acts of its subsidiary, including the parent corporation's exercise of control over the decision making of the subsidiary; the subsidiary's actions as an alter ego of the parent corporation such that recognition of a distinct corporate entity would lead to fraud or an injustice or would defeat public policy and the interrelatedness of operations. While we do not believe that it is necessary to apply any single test that might be used in the context of assigning liability, we believe that some of the same considerations apply when trying to determine whether there is functional separateness among related or affiliated organizations.

The requirement for separate governing bodies, separate medical boards, separate medical officers, and separate chief executive officers in co-located hospitals under the same ownership does not prevent, on a practical level, the establishment of admission, treatment, and discharge policies that maximize payments. Some of these co-located facilities are under common ownership, either nonprofit or for profit, and, therefore, the payments generated from care delivered at both settings affect their mutual interests. Even when the hospital-within-a-hospital and the host hospital are separately owned, we believe that there may have been incentives to prematurely discharge patients to a post-acute care setting in spite of the fact that the acute care hospital could continue to provide the appropriate level of care. We found this situation even more troubling regarding LTCHs, in particular, because LTCHs are certified as acute care hospitals and the statutory and regulatory distinction between LTCHs and acute care hospitals is generally the greater than 25-day average length of stay criterion at §412.23(e)(2). In

many parts of the country, there are no LTCHs and appropriate care for patients who could otherwise be treated in LTCHs is being delivered in acute care hospitals, often followed by post-acute care at SNFs. Because a similar level of care is often available in either an acute care hospital or a LTCH, we believe that, when an acute care hospital and a LTCH are co-located, there are significant inducements for patients to be moved to the provider setting that generates the highest Medicare payments.

This movement of patients is facilitated by the fact of co-location because, rather than arranging for the patient to be admitted to another offsite facility and transporting the patient by ambulance to another hospital, all that may actually be required to "discharge" the patient from one hospital and admit the patient to another is wheeling the patient down the hall or on and off an elevator.

Although co-location of Medicare providers, at best, may embody the positive economic benefits of sharing expensive medical equipment and provide a measure of convenience for patient families, at worst, co-location and patient-shifting can serve to undermine the basic premise of the IPPS DRG classification system and generate inappropriate Medicare payments. This is the case because payment for specific diagnoses is determined by setting DRG weights that represent a national averaging of hospital costs for each diagnosis. In addition, the Federal standardized payment amount was based on the average cost of a patient across all hospitals. This assumes that, on average, both high-cost and low-cost patients are treated at a hospital. Although Medicare might pay a hospital less than was expended for a particular case, over a period of time, the hospital would also receive more than was expended for other cases.

However, an acute care hospital that consistently discharges a higher cost patient to a post-acute care setting for the purpose of lowering its costs undercuts the foundation of the IPPS DRG system, which is based on averages. In this circumstance, the hospital would recoup larger payments from the Medicare system than is intended under the DRG system because the course of acute treatment has not been completed. At the same time, the patient, still under active treatment for an acute illness, will be admitted to a LTCH, thereby generating a second admission and Medicare payment that would not have taken place but for the fact of co-location.

In the May 18, 2004 proposed rule, we indicated that we believe the 15-percent policy is being sidestepped through creative corporate reconfigurations. Therefore, if the LTCH is nominally complying with the 15-percent requirement, it has not been required to meet the basic hospital function requirements at existing §412.22(e)(5)(iii). Thus, it is free to accept even 100 percent of patients from the onsite host, and share the same basic hospital functions as the host. Reliance on meeting the 15-percent criterion has enabled the creation of LTCH hospitals-within-hospitals that rely upon affiliated entities both for their operations and for their patient referrals. This results in a situation very similar to the hospital-within-hospital serving as a LTCH unit of the acute care hospital, which is precluded by the statute.

One of the reasons we proposed revisions to the existing criteria for hospitals-within-hospital in the May 18, 2004 proposed rule was because we believe that determining whether a hospital has complied with the 15-percent criterion is burdensome for a fiscal intermediary on an ongoing basis. Presently, review of corporate

arrangements represents a snapshot in time that may assess a particular set of business transactions but does not provide relevant details to reveal the extent of the unity of interests between the parties over time. Further, the widespread existence of such complex configurations, as well as the ongoing creation of new business arrangements, convinced us that a hospital-within-a-hospital's compliance with §412.22(e)(5)(ii) may be fluid, unreliable, or, in some cases, nonexistent.

Another reason we proposed revisions to the existing criteria for hospitals-within-hospitals in the May 18, 2004 proposed rule is because the concerns that we expressed in 1994 and 1995, when excluded hospitals were paid under the reasonable cost-based TEFRA system, are even more compelling with the implementation of PPSs for LTCHs and IRFs, because now one episode of care for a beneficiary could generate two full Medicare prospective payments, one under the IPPS, and another under the applicable excluded hospital PPS. In addition, the substantial increase in the number of hospitals-within-hospitals adds further urgency to reevaluation of the existing hospital-within-a-hospital policies. Therefore, it is incumbent upon us to revise our regulations in order to offer the greatest possible protection against potential abuses.

Accordingly, for qualification purposes, we proposed to delete the 15-percent criterion at §412.22(e)(5)(ii) and the rarely elected criterion at §412.22(e)(5)(i) that required the hospital-within-a-hospital to perform basic hospital functions, which include nursing services, medical records, pharmacy services, radiology, laboratory services, infection control, and discharge planning, through the use of employees or under contracts or other agreements with entities other than the host hospital or a third entity

that controls them both. Because we believe that efficient use of excess space at a hospital and the sharing of medical facilities and services may represent the strongest argument for the existence of hospitals-within-hospitals, from the standpoint of efficiency and cost reduction, we do not believe that these criteria should be maintained.

We proposed that all hospitals-within-hospitals would be required to comply only with the criterion set forth at the existing §412.22(e)(5)(iii), which requires that at least 75 percent of the admissions to the hospital-within-a-hospital be referred from a source other than the host hospital. We believe that this "functional separateness" test (62 FR 46014, August 29, 1997) directly addresses our concern that the excluded hospital not function either as a vehicle to generate more favorable Medicare reimbursement for each provider or as a de facto unit. Compliance with the 75-percent criterion is a requirement that we can verify without the involvement of corporate attorneys and a yearly reevaluation of corporate documents and transactions. The goal of the proposed provisions was to diminish the possibility that a hospital-within-a-hospital could actually be functioning as a unit of an acute care hospital and generating unwarranted payments under the much more costly LTCH PPS.

Therefore, under the proposed policy in the May 18, 2004 proposed rule, a hospital must demonstrate that it has a separate governing body, a separate chief medical officer, and a separate chief executive officer, and that at least 75 percent of its admissions originate from a source other than its host hospital, in order to be totally excluded from the IPPS. Fiscal intermediaries would reevaluate compliance with these regulations annually. In implementing our belief that separation and control can best be

objectively determined by limiting compliance to the 75-percent criterion as the single "performance of hospital functions" test, we proposed several policy options that are detailed below that, if not met, notwithstanding compliance with the separate governance and control requirements under existing §412.22(e)(1) through (4), could result in the either total discontinuance of IPPS-exclusion payment status or Medicare payment adjustments for hospital-within-a-hospital patients from the host hospitals.

As noted above, DRG weights and hence payments under the IPPS are established annually based on the average concept that recognizes that, for patients with a particular diagnosis, some will stay longer and consume more hospital resources than expected, while others will have shorter, less costly stays. Under the IPPS, a full DRG payment is triggered on the first day of admission to the acute care hospital. Medicare adopted an IPPS transfer policy at §412.4(b) in order to pay appropriately for cases that were discharged to other IPPS hospitals prior to the hospitals delivering full treatment to a beneficiary. We also promulgated the post-acute care transfer policy at §§412.4(c) and (d) to discourage premature transfers or discharges from IPPS hospitals for particular DRGs to post-acute care settings, including LTCHs (63 FR 40977, July 31, 1998, 68 FR 45469, August 1, 2003). The issues that we addressed in formulating the acute and post-acute care transfer policies are similar to those we are raising as our present concerns: that the incentives of the IPPS could result in acute care hospitals shifting a portion of the cost of services that should reasonably be treated in that setting to other providers; that the acute care hospitals would still collect a full DRG payment under the IPPS for less than a full course of treatment; and that an additional and unnecessary

Medicare payment would be made to the second provider. We believe that the potential for linking clinical decisions to the highest Medicare payments is even stronger when the acute care hospital and a postacute care provider are co-located and, even more so, if they are also under common ownership.

Therefore, in the May 18, 2004 proposed rule, we also proposed to revise §412.22(e), effective October 1, 2004, to preclude common ownership (wholly or in part) of hospitals-within-hospitals and host hospitals (proposed new §412.22(e)(2)(ii)). However, we also proposed to "grandfather" those hospitals-within-hospitals that were under common ownership with their host hospitals prior to June 30, 2004, and to continue to pay them as hospitals excluded from the IPPS, as long as they comply with the existing control criteria at §412.22(e)(1) through (4) (as set forth in proposed new §412.22(e)(2)(i)) and with the proposed mandatory 75-percent criterion (as set forth in proposed new §412.22(e)(2)(iii)).

In addition, in the May 18, 2004 proposed rule, we presented, for public comment, three payment options that we believe would diminish the possibility of a hospital-within-a-hospital actually functioning as a unit of an acute care hospital and at the same time generating unwarranted payments under the more costly LTCH PPS.

Option 1. Under the first option, as discussed earlier, in order for a hospital-within-a-hospital to receive payment as an IPPS-excluded hospital, we proposed to retain as the only qualifying criterion that the hospital-within-a-hospital have at least 75 percent of its admissions from a source other than the host hospital (existing §412.22(e)(5)(iii)). The hospital-within-a-hospital would still be required to demonstrate

that it meets the separateness and control criteria at §412.22(e-). Under this option, a hospital-within-hospital that admitted more than 25 percent of its patients from the host hospital would not be paid as an IPPS-excluded hospital for any of its patients. The hospital or unit that does not meet the criteria under this option would receive payment as an acute care hospital for all of its patients.

As stated earlier, we believe that compliance with the 75-percent criterion under this option is a requirement that fiscal intermediaries would be able to evaluate annually in an efficient manner without the involvement of corporate attorneys and a yearly reevaluation of corporate documents and transactions. Further, we believe that this option would ensure increased protections to the Medicare program and greatly diminish opportunities for maximizing Medicare payments under the PPS.

Option 2. Under the second option, as we had proposed earlier, we would require the hospital to meet the existing qualifying 75-percent criterion under §412.22(e)(5)(iii). However, under this option, we would allow a hospital-within-a-hospital that failed to meet the 75-percent criterion to be paid as a PPS-excluded hospital only for the patients admitted to the hospital-within-a-hospital from providers other than the host hospital. For example, no payments would be made to a LTCH for those patients that had been transferred to the LTCH from the host hospital because it failed to meet this criterion. Payments for patients referred from the host hospitals would only be paid to the host under the IPPS. We would treat services provided by the hospital-within-a-hospital as services furnished "under arrangement." Therefore, in keeping with our existing policy at §411.15(m) that restricts separate Medicare payment to hospital services furnished

under arrangements, we would make payment only to the acute care hospital from which the patients were referred for "under arrangements" furnished by the hospital-within-a-hospital.

Option 3. Under the third option, as we proposed earlier, we would require that the hospital-within-a-hospital must meet the existing qualifying 75-percent criterion under §412.22(e)(iii). However, under this option, we would pay the hospital-within-a-hospital directly for services, even for services provided to patients admitted to the hospital-within-a-hospital from the co-located acute care hospital. However, the payment to the hospital-within-a-hospital for those patients would be the lesser of what would be paid under the IPPS for that DRG, or what would be paid to the hospital-within-a-hospital under the applicable excluded hospital payment system. Payments to the hospital-within-a-hospital for patients admitted to the hospital-within-a-hospital from another hospital that was not the co-located hospital would be made under the hospital-within-a-hospital payment system with no adjustment. Therefore, for example, a LTCH that was a hospital-within-a-hospital and failed to meet the 75-percent criterion would be paid the lesser of the IPPS payment or the LTCH PPS payment for its patients that were admitted from its host hospital. However, for patients admitted from other hospitals, the LTCH hospital-within-a-hospital would be paid under the LTCH PPS with no adjustment.

In the May 18, 2004 proposed rule, we indicated that we believe that adoption of any of these three options is within the broad discretion conferred on the Secretary by section 123 of Pub. L. 106-113 (BBRA) and by section 307 of Pub. L. 106-554 (BIPA),

which grant the Secretary the authority to develop a per discharge PPS for payment of inpatient hospital services by LTCHs and to provide for appropriate adjustments to the LTCH PPS.

We proposed to revise the existing separateness and control regulations at §412.22(e) for hospitals-within-hospitals and to require that in order to be excluded from the IPPS, all hospitals-within-hospitals must admit no more than 25 percent of their patients from the onsite host hospital. (See section §412.534.) We also proposed to preclude common ownership of host hospitals and excluded hospitals, while grandfathering existing hospitals-within-hospitals and hosts that are under common ownership, as long as they comply with the proposed mandatory 75-percent criterion. We further sought comments on the options presented if the hospital-within-a-hospital fails to meet the 75-percent criterion that would either require that all of the hospital's Medicare payment would be made under the IPPS or, alternatively, to allow a hospital-within-a-hospital to still be paid as an excluded hospital for its admissions from onsite providers while applying specific payment adjustments for patients admitted from the host hospital.

In the proposed rule, we solicited comments on the three options presented and whether they provide sufficient protection against the phenomenon of inadequate separateness and control as described in the proposed rule. We want to emphasize that, under any of the options, nowhere is a change in physician clinical decision making or a change in the manner in which a physician or hospital practices medicine intended. The

policy options outlined in the proposed rule simply addressed the appropriate level of payments once those decisions have been made.

Comment: One commenter expressed the opinion that the increase in the number of LTCHs is in part due to the conversion of IRFs to LTCHs that is due to the enforcement of the criterion for exclusion from the IPPS as a rehabilitation hospital or unit which is set forth in §§412.23(b)(2) and 412.30, and relates to the inpatient population treated by a hospital or unit. This criterion is frequently referred to as the "IRF 75-percent rule". In addition, the same commenter recommended that those IRFs and IPFs that are converting to LTCHs should first have to meet the length of stay requirements for exclusion as a LTCH by operating and being paid under the IPPS for 1 year. The commenter believed that such a requirement would be consistent with the LTCH PPS final rule published on May 7, 2004 (69 FR 25674), which the commenter described as requiring a satellite facility to qualify under the IPPS for 1 year.

Response: Our primary reason for disagreeing with the comment on this point is that the 75 percent rule as described in prior regulation is not currently being enforced. Until recently, as explained further below, our regulations at 42 CFR 412.23(b)(2) stated that, except in the case of a newly participating rehabilitation hospital seeking exclusion for its first 12-month cost reporting period, a hospital could qualify for exclusion from the IPPS and payment under the IRF PPS only if at least 75 percent of the inpatient population of the hospital required intensive rehabilitative services for one or more of 10 specified medical conditions. On June 7, 2002, CMS issued a memorandum to fiscal intermediaries instructing them to suspend enforcement of the 75 percent rule. After

further review of this issue, and notice and comment rulemaking on it, on May 7, 2004, CMS issued revised regulations, effective for cost reporting periods starting on or after July 1, 2004, which changed the list of qualifying medical conditions and, for a hospital's first cost reporting period beginning on or after July 1, 2004, require only a 50 percent compliance level. These regulations are set forth, and explained in detail, in the final rule published at 69 FR 25752.

Although we have heard anecdotally that some of IRFs have converted to LTCHs or are in the process of evaluating such a conversion, we have no objective evidence to support the view that such conversions are occurring in large enough numbers to be a significant factor in causing the recent increase in the number of LTCHs. Thus, while there may be many reasons for the growth in the number of LTCHs, we continue to believe that it is likely that this increase may have been induced to a significant extent by the establishment and implementation of a LTCH PPS.

We also considered, but do not agree with, the commenter's recommendation that IRFs and IPFs wishing to convert to LTCHs should first have to operate and be paid under the IPPS for a specified time period, described by the commenter as 1 year, in order to make the policies applicable to IRFs and IPFs consistent with 42 CFR §412.23(e)(4)(ii), as revised by the May 7, 2004 LTCH PPS final rule (69 FR 25706-25708) regarding a satellite facility (as defined in §412.22(h)) or a remote location of a hospital (as defined in §413.65(a)(2)) that voluntarily reorganizes as a separate Medicare-participating hospital. The regulations in §412(e)(4) are clear that the applicable average length of stay requirement for exclusion from the IPPS as an LTCH

can be satisfied only based on discharges that occur on or after the effective date of its Medicare participation as a separate hospital and not based on operating experience obtained when the facility was not itself a separate Medicare participating hospital but instead was a part of a larger institution which participated in Medicare as a hospital. However, a facility excluded from the IPPS as a rehabilitation hospital under 42 CFR 412.23(b)(2) is already a hospital as required by §412.23(e)(4), and its discharges can be used to determine whether it satisfies the applicable length of stay requirement. Thus, because the Medicare participation status of a separate rehabilitation hospital is different from that of a satellite or a remote location, consistency with §412.23(e)(4)(ii) does not require the change suggested by this commenter, and we have therefore not adopted that change in this final rule.

Comment: One commenter shared CMS' concerns regarding the potential for manipulation of the intent of the separateness and common ownership regulations, and was also in agreement that hospitals-within-hospitals should be prevented from functioning as units of acute care hospitals.

Response: We appreciate the commenter's support of our concerns regarding the current hospital-within-hospital policy and took the comment into account in developing this final rule. We are finalizing revisions to separateness and control regulations at §412.22(e) and adding a new regulation at §412.534, Special payment provisions for long-term care hospitals-within-hospitals.

We are limiting the finalized policy revisions addressing host hospitals and LTCH HwHs and also to satellites of LTCHs that is, of LTCH HwHs, or free-standing LTCHs

and not to other co-located PPS excluded hospitals). These policies, as were the existing policies, are also applicable to any type of host hospital, including IRFs.

We are finalizing policy to eliminate the existing three "Performance of basic hospital functions" options under existing §412.22(e)(5) for qualifying as a LTCH HwH or a LTCH satellite (the 15 percent rule and the basic functions test, and the 75/25 test). If a LTCH HwH meets existing separateness and control of administrative and medical governance provisions at §412.22(e)(1) through (e)(4), payment will be made under the LTCH PPS as specified in §412.534. Under §412.534, if a LTCH HwH or LTCH satellite's admissions from its host hospital exceed 25 percent (or the applicable percentage) of its discharges for the LTCH HwH or LTCH satellite's cost reporting period, an adjusted payment will be made at the lesser of the otherwise payable amount under the LTCH PPS or the amount that would be equivalent to what Medicare would otherwise pay under the IPPS. In determining whether a hospital meets the 25 percent criterion, patients transferred from the host hospital that have already qualified for outlier payments at the host would not count as part of the host's 25 percent (or the applicable percentage) and therefore the payment would not be subject to the adjustment. Those patients would be eligible for full payment under the LTCH PPS. (Cases admitted from the host before the LTCH crosses the 25 percent threshold would be paid an otherwise unadjusted payment under the LTCH PPS.)

We are finalizing additional adjustments to the 25 percent policy for specific circumstances. For rural host hospitals with LTCH HwHs or LTCH satellites, instead of the 25 percent criterion, the majority (that is, more than 50 percent) of the patients would

have to be from hospitals other than the host. In addition, in determining the percentage of patients admitted from the host, any patients that had been Medicare outliers at the host and then discharged to the LTCH HwH or LTCH satellite would be considered as if they were admitted from a non-host hospital. For urban single or MSA dominant hospitals, we would allow the LTCH HwH or LTCH satellite to admit from the host up to the host's percentage of total Medicare discharges for like hospitals in the MSA. We would apply a floor of 25 percent and a ceiling of 50 percent to this variation. In addition, in determining the percentage of patients admitted from the host, any patients that had been Medicare outliers at the host and then transferred to the LTCH HwH or LTCH satellite would be considered as if they were admitted from a non-host hospital.

In this final rule, after further analysis and consideration of the commenter's concerns, we have made various changes in the proposed policy as detailed later in this section. We have provided a 4-year transition for existing LTCH HwHs or LTCH satellites that will provide a reasonable period during which the host and the LTCH HwH or LTCH satellite will be able to adapt to the requirements of the new policy. Also included in this policy are LTCHs-under-formation that satisfy the following two-prong requirement: the hospital was certified as an acute care hospital on or before October 1, 2004, under Part 489; and was designated as a LTCH before October 1, 2005. For cost reporting periods beginning on or after October 1, 2004 through September 30, 2005, these hospitals will be grandfathered, with the first year as a "hold harmless." Therefore, grandfathered LTCH HwH or LTCH satellites will only need to continue to meet the existing separateness criteria at §412.22(e) which includes compliance with either

paragraphs (e)(5)(i)(ii), or (iii) for that first cost reporting period. However, we are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period. Therefore, while we are grandfathering existing LTCH HwHs and allowing for a 4-year transition, beginning on or after October 1, 2004 and before October 1, 2005 (FY 2005), those hospitals may not increase the percentage of discharges admitted from the host in excess of the percentage that they had admitted in FY 2004. After the first grandfathered cost reporting period, these LTCH HwHs will be required to meet a percentage transition over the 3 years beginning in FY2006. For the second year (cost reporting periods beginning on or after October 1, 2005 but before October 1, 2006), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006 but before October 1, 2007), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period beginning or 50 percent, and finally 25 percent (or other applicable percentage) beginning with the third year (cost reporting periods beginning on or after October 1, 2008.

Comment: Several commenters believed that hospitals-within-hospitals have grown in numbers because they are a more efficient and less expensive model. The commenters further stated that these providers are cost-effective and convenient for

physicians associated with both the hospital with a hospital and the host hospital, and state that the location and ability to work closely with the acute care hospital leads to efficient usage of space and sharing of medical facilities and services. Another commenter noted that many hospitals-within-hospitals have strict admission standards; this is to ensure that a patient requires hospital-level care. One commenter pointed to a report compiled over a 6-month period across all provider types that asserted that the Medicare program saved money for all LTCHs regardless of their designation as freestanding or hospital-within-hospital. Under the circumstances, the commenter believed that CMS should not place restrictions on patient access to beneficial care through the application of a cap on the percentage of host hospital admissions.

Response: As we discussed in the proposed regulation, even though the co-location of Medicare providers may possibly have some positive economic benefits to both hospitals, such as the sharing of expensive medical equipment as well as provide a measure of convenience for patient families, at its worst, co-location and patient shifting can serve to undermine a basic premise of both the IPPS and the LTCH PPS, "which is that a single discharge-based PPS payment is adequate and appropriate reimbursement for the entire bundle of services that a hospital provides during the course of a patient's stay." (69 FR 28275). That is, with the implementation of PPS for LTCHs, now one episode of care for a beneficiary who is transferred from an acute care hospital to a co-located LTCH could generate two full Medicare prospective payments, one under the IPPS, and another under the applicable excluded hospital PPS.

As we had discussed previously in the September 1, 1994 final rule implementing the original hospital-within-hospital criteria, we believe a long term care hospital-within-a-hospital that is not adequately separated from the facility with which it is co-located is "essentially a long term care hospital unit that accounts for only a part of the larger hospital's patient load. Exclusion of long-term care units [from the IPPS] could inadvertently encourage hospitals to try to abuse the prospective payment systems, by diverting all long-stay cases to the excluded unit, leaving only the shorter, less costly cases to be paid for under the prospective payment systems. In such cases, hospitals would profit inappropriately from prospective payments." (59 FR 45389).

"Moreover, exclusion of long term care "units" is inconsistent with the statutory scheme. Section 1886(d)(1)(B) of the Act clearly provides for exclusions from the prospective payment system for psychiatric and rehabilitation units, but the statute does not provide for exclusion of long-term care units. Because we believe such exclusions are contrary to the purpose and scheme of section 1886(d)(1)(B) of the Act, we proposed to revise the regulations to prevent inappropriate exclusions." (56 FR 45389). Notwithstanding the commenter's concerns, we continue to believe that a revision to the current hospital-within-a-hospital policy is necessary in order to prevent potential abuses to the Medicare program.

Comment: Several commenters that noted that, although existing separateness and control regulations at §412.22(e) govern all hospitals excluded from the IPPS and our proposed changes would apply to all types of hospitals-within-hospitals, the concerns underlying our proposed revisions actually focus on the particular relationship between a

host acute care hospital and a co-located LTCH. The commenters requested that we limit any revisions in the hospitals-within-hospitals regulations to address that particular configuration. Two other commenters recommended the exclusion of children's hospitals because this policy could impose a significant potential barrier to children's hospitals' ability to respond to the growing demand for their services for the children of their regions, as well as to receive adequate payment from other payers.

Response: As we noted above, in the September 1, 1994 IPPS final rule (59 FR 45389), our concern with the "new" phenomenon of hospitals-within-hospitals and the ensuing separateness and control regulations that we established were originally directed at the relationship between a host acute care hospital and a co-located entity that was seeking State licensure and Medicare participation as a hospital, and then after demonstrating that it has an average length of stay of over 25 days, would obtain an exclusion from the IPPS and designation as a LTCH. We believed that the effect of this process would be an extension of the long-term care hospital exclusion to what was, for all practical purposes, a "long-term care unit." Only in the August 29, 1997 IPPS final rule did we extend the application of §412.22(e) beyond LTCHs to include other classes of facilities that might seek exclusion from the IPPS as hospitals-within-hospitals, including IRFs (62 FR 46012, August 29, 1997).

Notwithstanding this extension of our hospital-within-a-hospital policy, our data reveal that the vast majority of hospitals-within-hospitals are LTCHs and the considerable growth, discussed above, is in the number of new LTCH hospitals-within-hospitals. Thus, because we believe this to be a significant issue with regard to LTCH

HwHs or LTCH satellites (as seen by the increase in the number of LTCH HwHs or LTCH satellites), at this time, we will be limiting the scope of this policy only to LTCH HwHs (and also to satellites of LTCHs, as noted elsewhere in these responses). Although we will continue to monitor the establishment of other excluded hospital groups as well as LTCH HwHs or LTCH satellites, we are presently finalizing revised regulations targeted to the unique relationship between LTCH HwHs or LTCH satellites and host hospitals. We believe that this is necessary and appropriate because we are concerned about the potential for LTCH HwHs or LTCH satellites to, in effect, function as units of the host, and there is no statutory authority for LTCH "units" excluded from the IPPS under section 1886(d)(1)(B) of the Act but there is for the establishment of IRFs and psychiatric units of acute care hospitals. Therefore, historically, it has been less likely that an acute care hospital will be co-located with a free-standing IRF or psychiatric hospital as a HwH or satellite since the acute care hospital can establish its own rehabilitation or psychiatric unit. However, the fact that an acute care hospital is precluded from establishing its own LTCH "unit" may account for an increase in the number of separately certified co-located LTCHs at acute care hospitals.

In addition to this statutory basis, our concern with LTCHs existing as LTCH HwHs or LTCH satellites continues to be that an on-site LTCH can easily be utilized "seamlessly" as a step-down unit of the host hospital. A LTCH, in fact, is certified by Medicare and licensed by its State as an acute care hospital.(This is not the case where a patient is transferred from an acute care hospital to an IRF or psychiatric unit since the transfer of an acute care patient to an IRF or an IPF unit of the acute care hospital would

typically indicate a determination that there would be a clinical advantage to that patient's receiving highly specialized rehabilitation or psychiatric services otherwise unavailable at the acute care hospital.)

As we noted above, for an on-site LTCH, configured as a LTCH HwH or LTCH satellite, to actually function as a unit of the acute care hospital, despite the statutory preclusion, would undermine payments under the IPPS DRG classification system and generate inappropriate Medicare payments. This is the case because payments for specific diagnoses under the IPPS were determined by setting DRG weights that represent a national averaging of hospital costs for each diagnosis and assumes that, generally, both high-cost and low-cost patients are treated at a hospital. In addition, the Federal standardized payment amount was also based on the average cost of all patients across all hospitals.

Presently, because of the particular concerns that we have expressed, we believe that our policy revisions may relate more directly to LTCHs that exist as LTCH HwHs or LTCH satellites than to other excluded hospital designations. Therefore, although we will continue to monitor increases and changes in the HwH or the satellite "universe" and may revisit this issue in the future, the policy revisions for HwHs or satellites that we are finalizing in this notice will apply only to a situation where the HwH or satellite is a LTCH or a satellite of a LTCH.

Comment: Two commenters questioned whether a LTCH HwH or satellite or satellite that is co-located with an IRF would be subject to the separateness and control policies that we proposed.

Response: When we first addressed the existence of LTCH HwHs in the September 1, 1994 final rule for the IPPS (59 FR 45389), we were responding to the proliferation of a particular entity: a LTCH hosted by an acute care hospital. We expanded our definition of LTCH HwH to include all excluded hospitals in the September 1, 1995 final rule for the IPPS (60 FR 45836) because we recognized that co-location of other hospital types could give rise to payment concerns similar to those that we believed were likely to occur between a host hospital and a LTCH HwH. Therefore, although the vast majority of host/LTCH HwH arrangements are between acute care hospitals and LTCH HwHs, in §412.22 (e), we addressed circumstances under which a "hospital that occupies space in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital" will be excluded from the IPPS, but we do not specify a particular designation of excluded hospital.

Similarly, existing regulations at §412.22(e) do not specify what type of hospital the host hospital must be. Section 1886(d)(1)(B) of the Act, which establishes the distinction between a "subsection (d) hospital" and hospitals excluded from the IPPS, also includes a provision on grandfathering for certain HwHs and specifies that "[A] hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) [not a "subsection (d) hospital"] shall continue to be so classified notwithstanding that it is located in the same building as, or on the same campus as, another hospital." Although the statute establishes that certain HwHs will continue to be paid as an excluded hospital, the designation of the host is not limited.

(We did not receive any comments suggesting that we restrict the proposed regulations to only one type of host.)

We are presently limiting the finalized revisions to the separateness and control policy to LTCH HwHs, as noted in the previous response. Our concerns, as discussed earlier, about the relationship between a host hospital and a LTCH HwH or LTCH satellite would apply equally to situations where the LTCH HwH or LTCH satellite is co-located with either an acute care hospital or an IRF, and the existing statutory preclusion against the existence of LTCH units would also apply if the host hospital was an excluded hospital.

Therefore, we are clarifying that a LTCH HwH or LTCH satellite that is co-located with any hospital is subject to the revised regulations. We also want to note that even under existing LTCH HwH regulations at §412.22(e) or LTCH satellite regulations at §412.22(h), regardless of the designation of the host hospital, a LTCH that existed as a LTCH HwH that failed to meet requirements of (e)(1) through (e)(4) or one of the three performance of basic hospital functions tests at (e)(5)(i), (ii) or (iii) would have been paid under the IPPS. Similarly, if a satellite failed to meet the separateness criteria under §412.22(h), the satellite would also be paid as an acute care hospital under IPPS.
We have established in this final rule, under §412.534, that if a LTCH HwH or LTCH satellite admits more than 25 percent (or the applicable percentage) of its patients during a cost reporting period from its host, Medicare will pay an adjusted LTCH PPS payment based on the lesser of the otherwise unadjusted LTCH PPS rate or an amount equivalent to what would have otherwise been payable under the IPPS for each discharge. (Since

LTCHs are certified as acute care hospitals, we believe that this is an appropriate policy determination.) Furthermore, this payment policy is applicable in all situations where a LTCH HwH or a LTCH satellite is co-located with another hospital.

Comment*:* One commenter noted that the proposed revision of the separateness and control policy at §412.22(e)(v)(2)(iii) calculates the 75 percent of patients that must be "referred to the hospital from a source other than hospital occupying space in the same building or on the same campus" based on the "inpatient population" of the HwH. The commenter questions whether this limitation was intended to apply solely to Medicare beneficiaries. Two other commenters express concern that the proposed 25 percent rule, will affect admissions to the HwH directly from the host acute care hospital of even non-Medicare patients.

Response: When we first established the requirements at §412.22(e) to determine separateness between host hospitals and LTCHs in the September 1, 1994 final rule for the IPPS (59 FR 45389), the average length of stay calculation for purposes of designation as a LTCH was based on an average inpatient length of stay of greater than 25 days as calculated under paragraph §412.23(e)(3)(i) implementing section 1886(d)(1)(B)(iv)(I) of the Act. Under (then) §412.23(e)(3)(i), the calculation was determined by "dividing the number of total inpatient days (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period." With the implementation of the LTCH PPS, we revised the regulations at §412.23(e)(2)(i) and (e)(3)(i) to calculate the average length of stay based solely on Medicare patients, a change which we believed was more in keeping with the

establishment of a specialized PPS for Medicare patients who required long-stay hospitalizations at LTCHs. (See 67 FR 55970, August 30, 2002.) (We did not change the formula for calculating the average length of stay for an LTCH governed by section 1886(d)(1)(B)(iv)(II) of the Act, implemented at §412.23(e)(2)(ii), for a "subclause (II)" LTCH because we believed that in establishing a "subclause (II)" LTCH the Congress provided an exception to the general definition of LTCHs under subclause (I), and we had no reason to believe that the change in methodology for determining the average inpatient length of stay would better identify the hospitals that the Congress intended to excluded under subclause (II)). See 67 FR 55974, August 30, 2002.)

When we proposed the recent revision to existing regulations at §412.22(e)(5)(iii), we intended to apply the revision to the existing regulations and calculate the percentage of patients admitted to the LTCH from the host based solely on Medicare inpatients in conformity with §412.23(e)(2)(i) and (e)(3)(i). We appreciate the commenter's bringing this to our attention, and we will revise the regulation text to reflect that the 25 percent or other applicable percentage test will only apply to Medicare patients. (Since qualification of LTCHs under §412.23(e)(2)(ii) is not based only on Medicare patients, the LTCH HwH provisions at §412.534 would not apply to these hospitals.) We would also note that by restricting the calculation of the percentage of patients so it will be based solely on Medicare patients for the purposes of complying with payment under the 25 percent or other applicable percentage test (new §412.534), we have, in effect, assumed that payment to the LTCH may be affected by the number of Medicare patients that a LTCH HwH or LTCH satellite admits from the host hospital but will not be impacted by the

LTCH HwH or LTCH satellite admitting any number of non-Medicare patients from the host hospital because the number of non-Medicare patients will have no effect on a LTCH HwH or LTCH satellite's meeting the 25 percent or other applicable percentage requirement.

In addition, as discussed later in this preamble, we are finalizing a policy to count discharges from the host that had achieved outlier status at the host prior to being admitted to the LTCH HwH or LTCH satellite, as if they were LTCH patients from other than the host. Because that determination is not possible for non-Medicare patients, we are only applying the 25 percent test to Medicare patients.

Comment*:* One commenter challenged our concern that inappropriate patient shifting from a host acute care hospital to a LTCH hospital-within-a-hospital could result in undermining the IPPS by noting that even if such behavior is taking place, the annual reweighting of DRGs is a self-correcting mechanism for the IPPS that works to adjust payments to approximate costs.

Response: The "self-correcting" remedy noted by the commenter could in theory provide considerable protection to the integrity of the IPPS-DRG system, if all acute care hospitals hosted LTCH HwHs because charge data gathered for purposes of recalibrating DRG weights would be based on equivalent or at least similar circumstances throughout the nation. However, according to our most recent data, there are less than 130 LTCH HwHs as of June 2004 and approximately 4000 acute care hospitals. The charge data gathered from the acute care hospitals that are used to recalibrate the DRG weights is data for the full range of patients within each DRG across all acute care hospitals in the

nation. Because in the vast majority of these hospitals, the acute care hospital does not have a co-located LTCH hospital-within-a-hospital, the DRG weight for a specific DRG is reflective of the higher cost of hospital-level care for the types of patients that in relatively few hospitals may be treated at LTCHs. Therefore, Medicare payments to the overwhelming majority of acute care hospitals without LTCH HwHs that will continue to treat a patient for the entire episode of care and which may ultimately become a high-cost outlier discharge would be the same for a particular DRG as it would be to one of the relatively few acute care hospitals that hosts a LTCH hospital-within-a-hospital and has the option of discharging a patient to the hospital-within-a-hospital prior to the full provision of clinical services to that same patient. In that situation, Medicare would have overpaid the acute care hospital under the IPPS (and the admission to the LTCH HwH would generate an additional payment under the LTCH PPS) for the same episode of care that in most parts of the country would have been delivered solely at the acute care hospital. Therefore, although the IPPS relies on the "self-correcting" nature of the DRG system for annual recalibration, we continue to believe that since there are so few acute care hospitals that have co-located LTCHs, this mechanism is not an effective remedy for such situations.

Comment: Several commenters suggested that the existing post-acute transfer policy already address many of the concerns with inappropriate payments under the IPPS in situations where a patient is discharged to a LTCH hospital-within-a-hospital while the patient is still under active treatment at the co-located acute care hospital. Further, the commenters suggested an expansion of the existing post-acute transfer policy to include

DRGs of patients frequently discharged from acute care hospitals to LTCHs as an alternative remedy to our proposed policies revising separateness and control policies for hosts and hospitals-within-hospitals. The commenter noted that this policy was mandated by statute and is the "primary vehicle" that Congress has chosen to deal with "substitution of service questions."

Response: The post-acute transfer policy at §412.4(c) which implemented section 1886(d)(5)(J) of the Act, stipulates that if an acute care hospital discharges a case assigned one of a specified groups of DRGs to a post-acute setting, such as a LTCH, prior to reaching the geometric means length of stay for that particular DRG, the discharge is considered to be a "transfer" and the Medicare payment to the acute care hospital under the IPPS is adjusted reflecting that less than a full course of treatment had been delivered.

In developing the revised separateness policy, we have looked at data from our 1996 through 2003 MedPAR files, focusing our data analyses on changes in lengths of stay that exceed the geometric mean length of stay for various DRGs at acute care hospitals with hospitals-within-hospitals as compared to those without hospitals-within-hospitals.

Our concern is that rather than just transferring patients before the geometric mean length of stay, which could be subject to a transfer policy adjustment if the case was assigned to one of the specified 29 DRGs, in general, we believe that these acute care hospitals are often discharging their patients to the onsite LTCH so as to reduce the length of stay of outlier patients. If the patient is discharged after the geometric mean ALOS, the payment for that patient would no longer be adjusted under the transfer policy. Accordingly, we do not believe that possible expansion of the existing post-acute transfer policy to other DRGs, which we discuss elsewhere in this final rule, would necessarily address the problem we are attempting to address with the 25 percent or other applicable percentage provision.

Comment: Four commenters asserted that our concerns about inappropriate payments to LTCHs under Medicare are already being addressed through several policies which are already in place: the post acute transfer policy under the IPPS which limits reimbursement to host hospitals when a patient is transferred to a LTCH; both the 3-days or less and the greater than 3-day interruption of stay policies under the LTCH PPS, the onsite discharge and readmission policy under the LTCH PPS; the greater than 25-day average length of stay policy for LTCHs; the short-stay outlier policy under the LTCH PPS; and requirements for medical necessity review. Finally, another commenter recommended a reduced payment methodology for host acute care hospitals discharging patients early to LTCH HwHs. That is, the early discharge could be addressed with the geometric mean length of stay; an edit could monitor the length of stay; and if early discharge occurs, the commenter suggested converting the PPS per discharge payment to a per diem payment.

Response: The existence of the policies noted by the commenters confirms the fact that, as PPS policies have evolved, we have continually been concerned about the issue of inappropriate Medicare payments, particularly at points of intersection between various payment systems. Although each policy establishes certain safeguards, none effectively address the concern that we are dealing with in this revision of hospitals-within-hospitals regulations: that of inappropriate patient movement from a host hospital to a co-located LTCH. As discussed above, the post-acute transfer policy at §412.4 ensures that a full DRG is not paid to the admitting IPPS hospital if a patient, whose diagnosis falls into one of a very limited number of categories, is transferred to an

alternative provider after an extremely short stay at the acute care hospital. Both the 3-day or less and the greater than 3-day interruption of stay policies at §412.531, as well as the onsite discharge and readmission policies at §412.532, are only triggered if a LTCH patient is discharged from the LTCH and is then subsequently readmitted to the LTCH after an interruption. These policies do not address our concern with inappropriate discharges from host hospitals to LTCH HwHs or LTCH satellites because they are focused on the site of care during the LTCH stay rather than on shifting care from the host to the LTCH HwH.

In response to the commenter's statement that the requirement that for LTCH designation, an acute care hospital must demonstrate that it has an average patient length of stay of greater than 25 days is another existing policy that protects against inappropriate payments to LTCHs, we would note that section 1886(d)(1)(B)(IV)(I) of the Act (implemented at §412.23(e)(2)(i)), is the specific statutory basis for of a LTCH as a type of acute care hospital that is excluded from the IPPS. This statutory definition only defines how long patients must stay on average at the LTCH, once they are admitted for the LTCH to maintain its IPPS exemption. It has no impact on the movement of patients from a host hospital to a LTCH HwH or LTCH satellite or the length of stay of that patient at the host before that patient is admitted to the LTCH. With this length of stay mandate in mind, however, at the outset of the LTCH PPS for FY 2003, we established the short stay outlier policy under the LTCH PPS at §412.529 to provide proportionately appropriate payments to LTCHs when patients receive treatment for considerably less than the statistically-defined average length of stay for a particular

LTC-DRG. This policy established a payment policy under the LTCH PPS for short-stays at the LTCH and does not address truncated stays at a host hospital (since this policy does not look to see if the stay at the host was truncated). The commenters mentioned medical review requirements at §412.508, a process that, at least presently, actually consists of a QIO reviewing a statistical sample of hospital records or is prompted by a specific incident-review request or appeal. Although the option of a retrospective QIO evaluation of medical appropriateness of a hospital discharge is always an option available to beneficiaries, we do not believe that such a specific situation provides significant protection for purposes of establishing payment policy under Medicare since so few discharges are actually subjected to QIO review.

Thus, as noted above, we do not believe that the results of any of these existing policies can effectively speak to the issues that we are addressing in the revised hospital-within-hospital policy. While we appreciate the commenter's recommendation concerning a reduced payment methodology for early discharges from the host acute care hospital, we do have an existing policy, the post-acute transfer policy discussed in the previous comment and response, that appears to be similar to what was described by the commenter. As we state above, we do not believe that even an extension of that policy addresses the issues we have identified here as the basis for the new separateness policy.

Comment: Two commenters stated that because the LTCH PPS was just implemented in October 2002, there has not been enough time to review the impact of this payment system on the industry. The commenters urged us to adopt the recommendations promulgated by MedPAC in its June 2004 Report to the Congress as

well as to conduct a serious study of the LTCH industry and to continue to monitor growth and payment issues prior to implementing additional regulations. Two other commenters supported a time-limited moratorium (3 years) on new LTCHs to allow QIO reviews to become well established and CMS research to be completed.

Response: Although we agree with much of what the commenter stated regarding the fact that the LTCH PPS is relatively new and the impact of the payment system on the industry is not yet certain, we do not believe that our regulations are premature. While we continue to monitor and evaluate the impact of the LTCH PPS on the LTCH industry, we believe that the policy revisions that we are finalizing in this rule arise from concerns with the host/ hospital-within-a-hospital relationship that have been present since our September 1, 1994 final rule (59 FR 45390) and, thus, predate the implementation of the LTCH PPS. These concerns have achieved new urgency with the considerable and continuing growth in the number of LTCH hospitals-within-hospitals. Although one method of dealing with our concerns is a time-limited moratorium on the establishment of new LTCHs, and hospitals-within-hospitals in particular, we believe that such a step is best left to the Congress. Even if this occurred, however, it would not address any problems occurring in existing hospital-within-hospital LTCHs. In addition to finalizing this separateness policy, however, we plan to continue our monitoring efforts and to publish a detailed evaluation of MedPAC's recommendations in **Federal Register** documents updating the LTCH PPS for rate year 2006.

Comment: Several commenters expressed concern that the policies that we proposed were based upon assumptions that were not supported by data. Three

commenters, in particular, included reports that were commissioned by industry groups, two of which evaluated data from specific LTCH chains that have hospitals-within-hospitals and one which analyzed MedPAR data for acute care hospitals from FY 2000. The data from one LTCH chain indicate that a large percentage of hospitals-within-hospitals admit considerably more than 25 percent of their patients from their host acute care hospitals. Another chain provided data indicating that, at least for its hospitals-within-hospitals, patients are generally reaching outlier status at the host acute care hospital prior to being discharged to the hospital-within-a-hospital. Data were also provided indicating that as a percentage of all of the host's discharges, the number of patients of the host that are discharged to LTCH hospitals-within-hospitals is extremely low (in the low single digits).

Response*:* We disagree with the commenters' statement that our policy revisions are not supported by data. Although we noted in the proposed rule that given the relatively recent implementation of the LTCH PPS, our data sources are relatively limited, the policies that we are finalizing for LTCH HwHs or LTCH satellites are the result of policy evaluations, anecdotal information, as well as data analyses. We also note, elsewhere in this preamble, that our concerns about the potential for inappropriate Medicare payments under the IPPS arising from the co-location of an acute care hospital and a LTCH, were first stated in the September 1, 1994 final rule for the IPPS (59 FR 45389).

When we proposed the regulations that we are finalizing in this document regarding LTCH HwHs, we noted that we were proposing to revise payment policies for

LTCH HwHs because we had become aware that, along with the considerable growth in their numbers, there was a trend indicating widespread corporate reconfigurations affecting the host/LTCH HwH relationship, particularly with regard to LTCH HwH. The existence of websites sponsored by industry consultants urging underutilized acute care hospitals to increase profits by renting space to LTCH HwHs in order to reduce the number of long-stay patients, further added to our concern

Since we first became aware of the existence of LTCH HwHs in 1994, we have been aware of the strong resemblance that they bore to LTCH units of acute care hospitals, a configuration precluded by statute. We believe that it is incumbent upon us to continually refine our payment systems in light of concerns about the continued viability of the Medicare Trust Fund. In finalizing the revised LTCH HwH policy, therefore, as discussed previously in this preamble, we believe that this policy will help to protect the integrity of the IPPS DRG system as well as discouraging inappropriate payments under the LTCH PPS, the system that provides for the highest per discharge payment to a provider in the Medicare program. These policy goals typically require both proactive as well as reactive decisions on our part. We are aware that the majority of LTCH HwHs presently admit considerably more than 25 percent (or the applicable percentage) of patients from their host hospitals and have taken that fact into account when we designed the transition policy for existing LTCH HwHs or LTCH satellites described elsewhere in these responses.

Nothing in our data analyses was contradicted by the above-mentioned studies sponsored by the LTCH industry. In finalizing the separateness policy in this regulation,

we are aware that not all hosts with LTCH HwHs or LTCH satellites are manipulating their discharge patterns in order to avoid reaching outlier status. In response to the commenter that suggests we use, as a qualifying criteria, the percent of the host's patients that are admitted to the LTCH HwH, our data verifies that as a percentage of the total number of patients the host discharges, the percentage that are discharged to LTCH HwHs or LTCH satellites, is low. But this is logical and to be expected since most LTCH HwHs or LTCH satellites consist of approximately 25 beds in contrast to significantly larger host hospitals. However, we are focusing on the percentage of patients admitted to the LTCH HwH or LTCH satellite from the host and since data from the LTCH HwH indicates that even the relatively small percentage of the host's patients (as a fraction of all the host's patients) is sufficient to assure that most if not all of the relatively smaller LTCH beds are occupied, we are concerned with the appropriateness of payments to the LTCH based on our existing policy for those patients, and we believe that our new policy is warranted.

In analyzing the discharge data, we have looked at data from 1996 through 2003 from our MedPAR files, focusing our data analyses on changes in lengths of stay that exceed the geometric mean cases at host hospitals that are co-located with LTCH HwHs or LTCH satellites as opposed to those without LTCH HwHs or LTCH satellites. Our concern is that, in general, a significant volume of these cases are being discharged to the onsite LTCH prior to reaching outlier status. We compared the number of Medicare covered days for specific DRGs with data from hospitals before and after they became a host hospital. We selected DRGs that MedPAC had identified as being more likely to

lead to cases in which a host hospital would transfer the patient from the acute care hospital to their co-located long-term acute care facility.

Acute hospitals were grouped into cohorts for each year from 1996 through 2003: those that were freestanding as distinct from those that currently were hosting a long-term care hospital. For all but one DRG (482), the mean amount of covered days across all years for hospitals that were currently hosting a LTCH was lower in comparison to when they were not hosting a LTCH. Four DRGs (263, 265, 266 and 483) experienced decreases over ten percent. We also looked at covered days for DRGs 483, 126, 264, and 475 for the year 1999 (since all the acute care hospitals in the analysis were not hosting LTCH HwHs or LTCH satellites that year) in comparison to 2002 and 2003 (because all the acute care hospitals in the analysis were hosting LTCH HwHs or LTCH satellites in those years). For most of these DRGs (particularly DRG 483), the number of discharges with a very high number of Medicare days decreases quite significantly at the acute care hospital after it became a host. We believe that this data indicates a correlation between the presence of a LTCH as a LTCH HwH or a LTCH satellite within an acute care hospital and a shorter length of stay for Medicare beneficiaries at the acute care hospital.

We, therefore, believe that the regulations that we are finalizing represent a reasonable response to our continuing policy concerns, industry monitoring, anecdotal information, as well as an evaluation of our available data. As additional data is gathered, we will continue our monitoring and analytic activities and determine whether additional policy revisions or refinements may be warranted.

Comment: One commenter asks whether satellites of HwHs will be required to meet the 25 percent test regarding their relationship with their host hospital.

Response: Although we did not explicitly discuss the impact of the proposed change on satellites, we believe that since satellites are also parts of a hospital that is within another hospital, it is appropriate to require that satellites of LTCHs meet the 25 percent or other applicable percentage test regarding discharges admitted from their host hospitals. These satellites may be linked either to LTCHs that are also co-located with a host hospital, that is, a LTCH HwH or LTCH satellite, or they may be a satellite of a free-standing LTCH. Under the current regulations, we have developed requirements for satellites of excluded hospitals at §412.22(h) that have generally mirrored those we have required for LTCH HwHs at §412.22(e) (64 FR 41532, July 30, 1999; 67 FR 50105, August 1, 2002) except for the application of the 15 percent requirement, discussed in detail above, because attempting to apply this 15 percent test could actually serve to undermine separateness and control rules already in effect for a satellite and a host. In the August 1, 2002 final rule for the IPPS, we stated, that "[S]ince the costs for the entire excluded hospital (at both the main hospital and the satellite facility) are reported on one cost report by looking at the costs that are shared between the satellite facility and the acute care hospital, the costs of services that the satellite facility receives from its 'host' hospital will invariably be less than 15 percent of the costs of the entire hospital, even if all the costs of the satellite facility were incurred by the host hospital." (67 FR 50106).

As we are finalizing regulations that abandon reliance on the 15 percent test as an indicator of separateness and control for LTCHs, and rather establishing the 25 percent or

other applicable percentage test as the determinant of "functional separateness" between a LTCH HwH or LTCH satellite and its host hospital for determining the appropriate payment level for LTCH patients admitted from the host, we are also establishing this same requirement for satellites of LTCHs under new regulations at §412.534. There is a considerable similarity between a LTCH HwH and a LTCH satellite, notwithstanding that satellites are "parts of a hospital" and HwHs are distinct facilities. We believe that the same concerns that we have expressed throughout this preamble regarding the potential for medically-unwarranted patient shifting between a host hospital and a LTCH HwH or LTCH satellite resulting in inappropriate Medicare payments are also present when an acute hospital is co-located with a satellite of a LTCH. In the July 30, 1999 IPPS final rule, when we stipulated that satellites of excluded hospitals would be required to meet the PPS exclusion requirements applicable to a hospital or unit, we noted that requirements for separate identification of the beds, patients, and costs of the satellite "closely parallel similar requirements applicable to all excluded units under §412.25(a)(3) and (a)(7) through (a)(12)." Therefore we believe that there are both administrative and procedural precedents for the application of separateness requirements to satellites. Accordingly, we have revised the regulations to clarify that the separateness policy applies to LTCH satellites under new §412.534, as well. In order for a LTCH satellite to be included in the grandfathering provision and payment policy phase-in, under §412.534, which we have established for certain LTCH HwHs, discussed in detail below, the LTCH satellite will have had to be in existence by October 1, 2004. (Note: Satellites do not have a 6-month qualifying period.) If a LTCH satellite does not meet

that requirement, (that is, if it is established after October 1, 2004) Medicare payments will be governed by §412.534(a) through (e). In determining whether the satellite meets the 25 percent (or other applicable percentages, discussed earlier) threshold, we would compare the total number of patients treated at the satellite location to the number of those patients that were admitted from the co-located host (subject to the outlier adjustment discussed earlier.)

Throughout this preamble, when we refer to this policy applying to LTCH HwHs, we intend this to apply as well to LTCH satellites that are co-located with a host hospital. In fact, a satellite location of a hospital is also co-located within another hospital.

Comment: Regarding our proposed policy precluding common ownership of an acute care hospital and a HwH, we received three comments in favor of the preclusion and ten comments urging us not to finalize this proposed policy. One commenter noted that where the LTCH is co-located but not commonly owned, the LTCH has no incentive to accept inappropriate patients from the host hospital. Two other commenters noted that that the financial incentive to accept inappropriate patients from a host hospital only exists when the acute care hospital and the LTCH are commonly owned, a situation that can exist even without co-location, that is, a freestanding LTCH, exempt from the requirements of §412.22(e) may be owned and governed by the hospital from which it receives the majority of its referrals. Three commenters expressed concern that in prohibiting common ownership of a host and a LTCH, we were unintentionally creating a regulatory preference for for-profit LTCHs. Another commenter stated that not-for-profit hospitals would particularly suffer from any preclusion of common ownership and since

LTCH "start-ups" already sustain financial loss because of the 6-month qualification period during which they are paid under the IPPS and, therefore, only if a community-based non-profit organization senses a real need in the community for LTCH services would it invest, develop and open an LTCH either as a HwH or free-standing. Two other commenters emphasized the distinction between ownership and control, noting that advantageous arrangements between entities that are not under common ownership could produce more "control" than would be present in a common ownership situation that is being administered in compliance with present regulations.

Several commenters requested that if we finalized the preclusions against common ownership, that we include in our proposed grandfathering provision, those HwHs that were "under development" to the extent that they were already operating as acute care hospitals within a host while collecting data that would enable them to qualify as LTCHs. Two of the commenters responded to our proposal to grandfather existing commonly owned hosts and HwHs while prohibiting the establishment of any new such arrangements by stating that grandfathering "any form of ownership or control by a related entity" would create inequity among providers as well as perpetuate any potential or existing abuses of Medicare policy. Two other commenters focused on the particular situation facing rural referral centers and sole community hospitals, two distinct categories of acute care hospitals that serve in unique markets and requested that even if our proposed policy prohibiting common ownership was finalized, that an exception be granted in these situations where there may be no other alternatives than for these isolated facilities to develop their own LTCHs. Another commenter further asserted that our

present policies for separateness and control, which also governs commonly owned hosts and LTCH HwHs are sufficient and effective.

Response: We thank the commenters that endorsed our proposed policy to prospectively preclude common ownership of a host hospital and a LTCH HwH. Our goal in proposing this policy was based on our concern that common ownership of a host hospital as well as a HwH (in particular, a LTCH) could result in revenue-driven rather than medically necessary discharge and admission determinations between the commonly-owned facilities that were also co-located since the benefits would accrue to one corporate entity. In response to another commenter, we are also aware that even in the absence of common ownership, or if a commonly-owned host and a HwH were being administered in strict compliance with existing policies, the host/LTCH HwH configuration where each component is separately owned could provide inappropriate benefits to each facility. (For example, as noted elsewhere in this preamble, we are familiar with internet advertisements sponsored by certain consultants and hospital corporations that specialize in LTCH HwH that urge underutilized acute care hospitals to decrease or eliminate their high cost outliers by leasing space to a LTCH HwH, a result which would lead to inappropriate Medicare payments to both the host as well as the LTCH HwH.) We also acknowledge the commenters that noted that common ownership, even between hospitals that did not share a location, could result in incentives for patient discharges and admissions more related to reimbursement than for clinical purposes. From the initial implementation of the LTCH PPS in 2002, we established on-going monitoring as an essential component of the LTCH PPS (67 FR 56014, August 30, 2002)

and we will continue to review data from varieties of LTCHs that reflect discharge and admission patterns from other Medicare providers: LTCH HwHs that are under common ownership with hosts and LTCH HwHs that are independently owned, as well as free-standing LTCHs, in order to evaluate whether further regulation may be necessary in order to address inappropriate Medicare payments. In response to the commenter who noted that a common-ownership preclusion would particularly affect not-for profit acute care hospitals that already have sustained a financial loss because any LTCH must be paid under IPPS for 6 months, we would respond that the qualifying period for LTCH designation is a requirement for all LTCHs, under §412.23(e)(3), both not-for-profit and for profit. After reviewing all of the comments, in this final rule, we are not finalizing the proposed policy precluding common ownership. In the proposed notice, we had offered a number of alternative policies to address the situation of a HwH that admitted more than 25 percent of its patients from its co-located host hospital. As an additional policy response to address this problem, we had proposed to regulate common ownership. However, we believe that because we are addressing our major concerns with commonly owned hosts and LTCH HwHs or satellites with the finalized 25 percent test which we believe will impact in the number and type of patients discharged from the host and admitted to the LTCH HwH, we do not need to also regulate against common ownership at this time. We will continue to monitor the common ownership issue and, if appropriate, revisit it at a later date. Therefore, one of the commenters that expressed concern regarding an “inequity” of competition between those LTCH HwH that would be subject to new regulation as opposed to those LTCH HwHs under common ownership

with their host that would be grandfathered, is no longer an issue. We have revisited the issue of common ownership, first discussed in the September 1, 1994, final rule for the IPPS (59 FR 45392) because, we did not agree with the commenter that asserted that our existing policies were "sufficient and effective " to address our concerns with the circumstance of common ownership. However, we do believe that our new revision of the entire separateness policy, set forth in the next response, is presently an adequate response to our significant policy concerns in the area of LTCH HwHs including commonly owned host/LTCH HwH arrangements. Since we are not finalizing the policy that precludes common ownership of a host and its LTCH HwH it is unnecessary to respond to those commenters that requested an extension of the proposed grandfathering provision and also to those commenters who believe that grandfathering of common ownership arrangements would perpetuate unnecessary abuses of the Medicare system. We will address other comments on grandfathering of existing LTCH HwHs unrelated to the common ownership issue elsewhere in these comments.

Comment: Several commenters urged us to retain the 15 percent criterion at existing §412.22(e)(5)(ii) and to strengthen both its enforceability as well as associated sanctions. One commenter objected to the change in policy and stated that if the 15 percent policy was enforced then "bad players" could be sanctioned. One of the commenters, a corporate officer of a LTCH HwH scheduled to open in August 2004 stated that complying even with the existing 15 percent rule would require turning away from "otherwise sound business practices." Two of the commenters further suggested that we extend separateness and control policies to limit specific business arrangements

such as loans or financial arrangements, whereby the host funds or contributes to the working capital of the LTCH HwH or reimburses operating expenses or losses; that the 15 percent rule be reframed as a preclusion with civil and/or criminal penalties attached in the event of violation; and that executive officers be required to file an annual attestations of compliance with separateness and control as part of the cost reporting procedure. Two commenters specifically suggest that we consider adopting provisions of the Sarbanes-Oxley Act of 2002 for the purposes of policing corporate financial reporting which includes requirements that CEOs and CFOs of public corporations certify via an attestation to the veracity of financial statements and disclosures with severe penalties for willful and knowing violations. The commenters believed that the attestation procedure, as well as the potential for civil or criminal liability, would shift the burden of enforcement of the 15 percent criterion from the fiscal intermediary to the providers. One commenter characterized our proposed policy as one that removes the 15 percent criteria, which can be monitored and replaces it with a test that is directly related to and acts to limit the admission and treatment of patients in need of hospitalization. On the other hand, there was one commenter who supported our proposal to strengthen separateness requirements and encouraged enforcement of existing requirements. The same commenter indicated an awareness of hospital systems setting up a co-located LTCH HwH that "on paper" appeared to meet our requirements but in effect was controlled by the host, leading to the on-site LTCH functioning as a unit. This commenter suggested that we require a written certification and supporting documentation verifying that the separation requirements have been met.

Response: When we established the regulations governing payment policy for hospitals within hospitals at §412.22(e) in the September 1, 1994 final rule for the IPPS (59 FR 45389) our goal was to create "a firewall" between the acute care host hospital and a new entity that we feared would actually function as a LTCH unit of that hospital, a statutorily precluded configuration.

As stated above in this preamble, in the May 18, 2004 proposed rule, we proposed to eliminate the 15 percent rule because we were aware that the vast majority of LTCH HwHs were choosing to comply with that option as opposed to the more rigorous separation of basic functions (for example, medical records, pharmaceutical services, radiological services, laboratory services (§482. 21 through §§482.27, 482.30l 482.42, 482.43, and 482.45) or the "functional separateness" test of the 25 percent referral requirement (62 FR 46014, August 29, 1997) and we did not believe that allowing a LTCH HwH to choose that the 15 percent rule among the existing policies regarding hospitals-within-hospitals had, in fact, sufficiently protected the Medicare program from the problems that we first envisioned in the September 1, 1994 final rule.

Moreover, queries from providers and consultants as well as information from fiscal intermediaries, and our regional offices, concerns expressed by MedPAC in its June 2003 Report to the Congress and at meetings held at outset of the implementation of the LTCH PPS (which was implemented for cost reporting periods beginning on or after October 1, 2002), and the recent growth in the LTCH universe, particularly LTCH HwHs, convinced us that it was incumbent upon us to revisit separateness and control policies. Furthermore, we were recently given the opportunity to review a number of

corporate documents, including Articles of Incorporation of existing host/LTCH HwH arrangements as well as pending arrangements for the establishment of LTCH HwHs. These reviews made us aware of the development of a new generation of complex and creative corporate reconfigurations that would make it difficult and burdensome, if not impossible, for our fiscal intermediaries to ascertain compliance with §412.22(e) based on the 15-percent policy. We want to note that we understand that many LTCH HwHs made every possible effort to comply with the 15 percent provision.

However, in response to commenters suggesting a range of options which preserve the 15 percent criterion, such as toughening the policies to prohibit specific business arrangements; the attachment of civil and/or criminal penalties in the event of violations; a requirement for annual attestations be required by corporate officers; adoption of particular corporate policing provisions of the Sarbanes-Oxley Act of 2002, we would note that retaining the 15 percent criterion, even under any of the proffered circumstances would be an administrative burden on CMS and its contractors since they would require extensive reviews, audits, and monitoring to ferret out the "bad players." We also want to note, in response to the commenter who expressed concern about having to depart from "sound business practice" in order to comply with the 15 percent rule, that it is our statutory responsibility under sections 1102 and 1871 of the Act to establish regulations as may be necessary to effectively administer the Medicare program. A hospital retains the ability to conduct its corporate affairs as it sees fit and to the extent that the hospital's behavior does not conform to Medicare payment requirements, the hospital has made a choice, since it has been put on notice that it will not be paid under

the regulations governing the Medicare program. The participation of a business in the Medicare program generally indicates that the provider has decided that the advantages of participation outweigh any adaptations in business practices required by our rules.

We now believe that allowing LTCH HwHs to qualify by complying with the 15 percent test did not operate to prevent the creation of LTCH HwH that were actually functioning as units of hosts. Further, even if at their creation, there was effective compliance with the 15 percent test, monitoring continued compliance was nearly impossible. But even if it were possible to accurately monitor a LTCH HwH or satellite's compliance with the 15 percent test, we now believe that meeting this particular test, would not sufficiently ensure that Medicare payments otherwise payable under the LTCH PPS, for LTCH patients admitted from the host (that exceed 25 percent (or the applicable percentage of the HwH's discharges)) are appropriate. Moreover, we consider that for Medicare payment purposes, the significant movement of patients between the host hospital and the LTCH HwH or satellite continues to be the most effective indication of whether they are functioning as distinct hospitals or whether, in violation of statutory intent, in fact, the configuration is resulting in these facilities behaving as acute care hospitals with sub-acute units.

As we previously stated, we want to reiterate that we are not substituting a criterion that will limit admission and/or treatment of Medicare beneficiaries by eliminating the 15 percent policy. We agree with the commenter who stated that our goal in establishing this policy revision was to prevent a co-located LTCH HwH or satellite from

appearing to comply with our requirements “on paper,” but actually to be controlled by and functioning as a unit of the host. In response to the same commenter, we would also note that under the finalized policy, submission of documentation to fiscal intermediaries regarding compliance with existing separateness and control policies under §412.22(e)(1) through (e)(4) is required to be paid as an IPPS excluded LTCH HwH or satellite under §412.22(h)(2)(D) and we will continue to require such documentation to demonstrate compliance with those requirements. As noted elsewhere in these responses, detailed instructions will be sent to fiscal intermediaries regarding implementation procedures for payment adjustments under new §412.534.

In this final notice, therefore, effective for cost reporting periods beginning on or after October 1, 2004, for LTCH HwHs we are eliminating the 15 percent test under existing §412.22(e)(5)(ii), and the performance of basic hospital functions test under subsection §412.22(e)(5)(i) and the 75 percent of admissions from other than the host criteria at §412.22(e)(5)(iii). If a LTCH demonstrates compliance with the medical and administrative separateness and control policies at §412.22(e)(1) through (e)(4), under our finalized policy, it will satisfy LTCH HwH

requirements. The 25-percent or other applicable percentage test, described in the next response, will be the threshold criteria for a new payment adjustment for LTCH HwHs or satellites in new regulations at §412.534.

Comment: We received numerous comments from LTCHs, industry groups, Congressional representatives, and individual medical professionals expressing great concern with respect to our various payment proposals, which are based on utilizing the 25 percent test. As proposed in the proposed rule, the 25 percent test would have been the sole determinant for a LTCH HwH or satellite to receive payment as a hospital excluded from the IPPS. We received several comments urging us not to adopt any of the proposed payment policies; that they were arbitrary and unprecedented and would result in lesser payments to the LTCH HwH or satellite based upon the source of patients. The commenters argued that reducing payments to the LTCH HwH or satellite for patients admitted from the host hospital beyond 25 percent of the LTCH HwH or satellite’s total annual discharges would have two highly negative effects. First, this policy would result in the denial of necessary and appropriate care to patients who could benefit from treatment at the LTCH HwH or satellite. Additionally, a

lower level of reimbursement would lead to the closing of LTCHs with all the attendant consequences of such closures such as shortage of hospital beds, industry insecurity leading to the inability to retain and attract professional staff, and loss of jobs for employees of the LTCH HwH or satellite. The policy that we are suggesting, several commenters assert, sets a “maximum limitation” on the admission of patients from the host, arbitrarily diverting patients away from LTCHs that share buildings with other hospitals.

A number of commenters stated that our proposed policy constitutes discrimination against certain LTCHs solely because of their location, and if finalized, will disrupt health care service delivery and also exert a destabilizing effect on patient care programs and capital projects. One commenter asserts that the location of a duly licensed hospital may not be utilized as a basis for excluding it from participation in the Medicare program as a LTCH. Several other commenters assert that there would also be an impact on the availability of intensive care unit beds in the acute care hospitals, creating

shortages which could threaten the availability of care for trauma patients in certain communities, if patients no longer needing these services were not discharged to onsite LTCHs.

Response: We do not agree with the commenters who interpret our regulations as establishing arbitrary and unprecedented limits on the right of a LTCH HwH to receive payment under the LTCH PPS. We are providing an adjustment to the payment under the LTCH PPS in accordance with the broad authority conferred on the Secretary by the Congress in section 307(b) of Pub. L. 106-554 to include "appropriate adjustments" in the establishment of a PPS for LTCHs. The finalized payment policies described below and the concerns that they represent echo concerns first expressed in the September 1, 1994 final rule for the IPPS, when we began to regulate new entities that we named "hospitals within hospitals." As noted elsewhere in these responses, the reason why we proposed the changes in the May 18, 2004 proposed rule at this time is the nexus between these decade-old concerns and the recent explosive growth in the numbers of LTCH HwHs. Furthermore, these regulations are grounded in a thorough review of the available data as well as exhaustive policy evaluations and are rationally related to the analyses of such information. In addition, we would emphasize most strongly that these regulations do not establish either arbitrary or unprecedented limits on the rights of a LTCH HwH or LTCH satellite to be paid under the LTCH PPS. Although we have made significant revisions to the policies in the May 18, 2004 proposed rule, our basic premise is unchanged.

As we first stated in that September 1, 1994 final rule, "we agree that the extent to which a facility accepts patients from outside sources can be an important indicator of its function as a separate facility, not merely a unit of another hospital. In general, a facility's functional separateness should be reflected in its ability to attract patients from sources other than the hospital that it serves. For example, if a facility receives all (or nearly all) of its admissions independently (that is, from outside sources), it can reasonably be assumed to be functioning separately from the host hospital. (59 FR 45391).

Having reevaluated the first two options that we presented in the May 18, 2004 proposed rule (69 FR 28326 through 28327) in light of comments that we received, we believe that the policy that we are finalizing is reasonable, and more directly addresses the relationship between movement of patients between the host hospital and the LTCH HwH or satellite and inappropriate or unnecessary Medicare payments, our central concern. Under the above policy, a LTCH must continue to demonstrate compliance with the medical and administrative separateness and control policies at §412.22(e)(1) through (e)(4). In the proposed rule, we stated that we would eliminate the two alternative qualifications for LTCH HwH (the 15 percent rule and the basic functions test) and instead rely solely on the 25 percent or other applicable percentage threshold for qualification purposes. We have refined this policy, in this final notice, and for purposes of qualifying as a LTCH HwH, we will eliminate all three performance of basic hospital functions options in §412.22(e)(5) if a LTCH HwH complies with §412.22(e)(1) through (e)(4) which addresses separateness and control of administrative and medical

governance, the LTCH will qualify as a LTCH HwH. Instead, the 25 percent or other applicable percentage test will be the threshold for a new payment adjustment for LTCH HwH in new regulations at §412.534, where Medicare payment policy under the LTCH PPS is promulgated and will apply to LTCH satellites as well. We are establishing a distinction in this new payment adjustment between patients admitted from the host and from sources other than the host because we believe that even if a facility satisfies the requirements of §412.23(e)(1) and (e)(2) and is eligible for payment as a LTCH and also satisfies revised §412.22(e)(1) through (e)(4) for purposes of being considered a LTCH HwH it may still appear to be functioning like a unit because of the number of patients that it admits from its host hospital. Payments will be made to the LTCH HwH or satellite for all Medicare patients under the otherwise unadjusted LTCH PPS only until the 25 percent or other applicable percentage threshold is reached after which point unadjusted (that is, not limited by a LTCH PPS payment amount that is equivalent to the amount otherwise payable under IPPS) payments will be made under the LTCH PPS for all Medicare patients admitted to the LTCH from sources other than the host. Once a LTCH HwH or satellite exceeds the 25 percent or other applicable percentage threshold, Medicare LTCH PPS payments for patients admitted to the LTCH from the host will be adjusted. This per discharge payment adjustment for patients from the host exceeding the threshold, will be based on the lesser of payments otherwise paid under the LTCH PPS or an adjusted payment under the LTCH PPS that is equivalent to the applicable payment that would otherwise be made under the IPPS. Payments for a non-host patients would continue to be made under the otherwise unadjusted LTCH PPS.

The policy that we will be finalizing is a variation of option III in the May 18, 2004 proposed rule and is applicable only to LTCHs governed under section 1886(d)(1)(B)(iv)(I) of the Act because the policy addresses payment policy related to the percentage of Medicare patients that are admitted to the LTCH HwH or satellite and as noted in a previous response, for a "subclause (II)" LTCH, the 25 percent test will not be applied because their certification as a LTCH is not tied to Medicare patients.

We believe that this policy captures the intent of section 1886(d)(1)(B)(iv)(I) of the Act which established LTCHs as a separate category of acute care hospitals for patients with average stays of greater than 25 days but precluded the establishment of LTCH units. To the extent that the source of its admissions reveal that the LTCH HwH or satellite is behaving like a unit of its host hospital, in contravention of both the statute and implementing regulations, Medicare will make adjusted per discharge payments under the LTCH PPS. When the facility appears to be functioning in compliance with the intent of the statute and implementing regulations, however, Medicare will make otherwise unadjusted payments under the LTCH PPS. In determining whether a hospital meets the 25 percent or other applicable percentage criterion, patients transferred from the host hospital that have already qualified for outlier payments at the acute host would not count as part of the host percentage. We believe that this is appropriate because as we discuss earlier in these responses, a patient reaching outlier status at a host hospital may be presumed to have received a full course of treatment in that setting. Further, in such a case, our policy presumes that a discharge to a LTCH HwH or satellite for post-acute care treatment may be clinically appropriate and therefore should reasonably be

eligible for otherwise unadjusted payment under the LTCH PPS. In addition, if a LTCH HwH or satellite exceeds the 25 percent or other applicable percentage threshold (with host outlier patients paid as non-host patients), Medicare will pay the lesser of the LTCH PPS payment or a reduced LTCH PPS payment based on an amount equivalent to what would otherwise be paid under the IPPS. (The adjustment would only be applied to discharged patients admitted from the host hospital that exceed the 25 percent (or the applicable percentage) threshold. Cases transferred from the host up to the LTCH applicable percentage threshold would be paid the unadjusted LTCH PPS rate.)

In this final rule, we have revised our use of the 25 percent test as a determinant of LTCH HwH satellite status that was originally set forth in the proposed policy and rather established it as a payment threshold under new §412.534. We have provided a 4-year transition for existing LTCH HwHs or satellites to allow for a reasonable period during which the host and the LTCH HwH or satellite will be able to adapt to the requirements of the new policy. Also included in this transition policy are LTCHs-under-formation that satisfy the following two-prong requirement: the hospital was certified as an acute care hospital on or before October 1, 2004, under Part 489; and was designated as a LTCH before October 1, 2005. We believe that these LTCH HwHs, since they have undergone significant efforts which could be adversely affected by these final rules, should be allowed a 4-year transition as well. For cost reporting periods beginning on or after October 1, 2004 through September 30, 2005, these hospitals will be grandfathered, with the first year as a "hold harmless." Therefore, grandfathered LTCH HwHs will only need to continue to meet the existing separateness criteria at §412.22(e) which includes

compliance with either paragraphs (e)(5)(i), (ii), or (iii) for that first cost reporting period. Grandfathered LTCH HwHs and LTCH satellites would not need to meet the 25 percent or other applicable threshold for the cost reporting periods beginning on or after October 1, 2004 through September 20, 2005. However, we are requiring that even for grandfathered facilities, in the first cost reporting period, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period. Therefore, we are grandfathering existing LTCH HwH and those LTCHs under-development that meet the 2 prong test and LTCH satellites that were in existence by October 1, 2004. Grandfathered HwHs and satellites may not increase the percentage of discharges admitted from the host in excess of the percentage they had in FY 2004. After the first grandfathered cost reporting period, these LTCH HwH will be required to meet a percentage transition over the 3 years beginning in FY2006. For the second year (cost reporting periods beginning on or after October 1, 2005, but before October 1, 2006), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006, but before October 1, 2007), the applicable percentage from the host will be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 50 percent, and finally 25 percent (or the applicable percentage) threshold will apply beginning with the fourth year (cost reporting periods beginning on or after October 1, 2007). We have adopted a transition of 75 percent, 50 percent, and then 25

percent since we felt it was reasonable to allow existing LTCH HwHs and HwHs under-development, as defined using the two-prong test above, 3 years to gradually meet our regulatory threshold.

Transitions are a frequently incorporated feature of new Medicare payment policies. Examples are the 4-year phase-in of the IPPS, the 5-year phase-in of the LTCH PPS, and the 3-year phase-in of the IRF PPS. In establishing a 1-year grandfathering as well as 3 additional years during which an existing LTCH HwH or satellite or "pipeline" LTCH HwH will be able to discharge the lesser of a proportionally-declining percentage or the hospital-specific percentage of Medicare patients that it admitted from its host during its final cost-reporting year prior to the implementation of this new 25 percent or other applicable threshold for the LTCH PPS payment adjustment, we are providing a reasonable and equitable methodology by which LTCH HwHs or satellites will be able to adapt to our new requirements.

Comment: Several commenters expressed concern about the impact of the proposed 25 percent test on rural hospitals. In particular, a commenter pointed out a situation where a single tertiary acute care hospital is the only provider for a multi-county area, capable of treating medically complex patients in the entire region and which hosts a LTCH HwH or satellite. In a rural county, for example, commenters assert that there would not be sufficient patient volume to support any other LTCH. In such markets, small or medium sized communities, the commenters maintain that our proposed 25 percent test would deprive communities of LTCH services or force construction of free-standing LTCHs.

Response: After considering the commenters' concerns and after further analysis, we are further revising the 25 percent criterion to provide for a payment adjustment for rural hospitals (§412.62(f)) or urban single or MSA-dominant hospitals (that is a hospital in an MSA that discharges more than 25 percent of all Medicare inpatient acute care hospital discharges in that MSA for like hospitals.) The Congress has authorized special treatment for rural areas under the Medicare program because of the particular geographic and demographic challenges in those locations as well as the differences between the provision and availability of medical services in rural as compared to urban areas. Further, in establishing this adjustment the Secretary is exercising the broad discretion granted by the Congress under section 307(b) of Pub. L. 106-554 to provide for appropriate payment adjustments in the LTCH PPS. Therefore, for rural acute care hospitals with LTCH HwHs or satellites, following the phase-in period, instead of the 25 percent criterion, we have provided that the majority, (that is, of at least 50 percent) of the patients would have to be from the hospitals other than the host. Where the majority of the patients are admitted from hospitals other than the host in this instance, since there are few other hospitals from which the LTCH HwH or satellite can admit inpatients, we believe the majority is a reasonable criterion to establish that the LTCH HwH or satellite is not acting as a unit of the acute hospital. As with other hospitals, any Medicare patient that had been at the rural host in outlier status and then transferred to the LTCH HwH or satellite would be treated as if the patient had been admitted from a non-host hospital in determining the percentage of patients admitted from the rural host hospital.

Additionally, for urban single or MSA dominant hospitals, which would generally be providing services under similar circumstances as rural hospitals, that is, being the only hospital in the area, we would allow the LTCH HwH or satellite to discharge Medicare patients admitted from the host up to the host's percentage of total Medicare discharges in the MSA for the most recent fiscal year that data is available for a hospital similarly certified as the host. We would apply a floor of 25 percent and a ceiling of 50 percent (representing a numerical majority of patients) to this group. We believe the maximum threshold of a majority of its patients admitted from the host indicates that the HwH is a separate hospital and is not operating as a unit of the host. For example, if there are only two acute care hospitals in the MSA and based upon the most recent data available, hospital A had 500 Medicare discharges in its fiscal year while hospital B had 1500 Medicare discharges, the total number of Medicare discharges for that MSA is 2000 discharges. If hospital B has a co-located LTCH HwH or satellite we would calculate its separateness percentage (that is, the percentage of Medicare patients that it could admit from the host for otherwise unadjusted LTCH PPS payments) based on its percentage of total Medicare discharges in the MSA. In this instance, hospital B has discharged 75 percent (1500/2000) of the discharges in the MSA. Accordingly, we would require that following the phase-in of the policy, the LTCH HwH or satellite be held to a determination that a ceiling of 50 percent (that is, less than a majority) of its discharges were admissions from the host hospital. Again, as previously noted, in determining the percentage of Medicare patients admitted from the host, as with all LTCH HwHs or satellites, any patient that had been in outlier status at the host and then transferred to the

LTCH HwH or satellite would be treated as if they were admitted from a non-host hospital.

As the above description of our revised payment policy for LTCH HwH or satellite demonstrates, we are not setting a "maximum limitation" on the admission of patients from the host. We are not establishing policies to prevent these facilities from delivering necessary and appropriate medical care and compliance with the policy need not result in hospital closures, industry insecurity, and a loss of professional and support staff. Instead, if the LTCH or satellite does not meet the applicable variation of the 25 percent test, rather than losing its ability to be paid as a hospital excluded from the IPPS in its entirety we will reduce Medicare payments under this policy only for those patients whose discharges exceed the threshold. Because hospitals will still be paid an appropriate amount for the care they deliver, we do not believe that those hospitals will close nor should there be industry insecurity or loss of professional or support staff. This reduction is to account for the fact that the LTCH is not functioning as a separate hospital but rather is effectively behaving as a unit. We would emphasize again that LTCH HwHs or satellites are free to admit any patient from any source without limit or restriction. In this policy revision, we merely address how Medicare will pay for patients in LTCH HwHs or satellites and establish the applicable thresholds that are the basis for such payment.

We disagree with the comment that suggests that we are "discriminating" against a hospital because of its location (within another hospital), we would respond that there are a significant number of Medicare payment policies that address certain hospitals for

"special treatment" because of their locations such as sole community hospitals (§412.92), rural referral centers (§412.96), and critical access hospitals (§413.70). Therefore, we believe it is appropriate to consider a hospital's location in determining payments. Similarly, it has been a long-standing practice to anticipate potential opportunities for "gaming" or to encourage behavioral change on the part of providers by establishing payment policies, often related to physical location, such as the onsite discharge and admission policy, under the TEFRA system for excluded hospitals at §413.40 (a)(3)(B) and under a similar policy in the LTCH PPS at §412.532. Further, in response to comments that suggest that the impact of our policy will be a disruption to health care delivery, patient care programs, and capital projects, we would state that we do not agree with these predictions. Rather, we believe that a reasoned analysis of the policies that we are finalizing, described in detail above, will reveal that they are neither destructive nor onerous to the effective functioning of either a host or a LTCH HwH or satellite.

Finally, with regard to the potential shortage of intensive care beds in the host and the possible consequential harm to the treatment of local trauma victims that commenters threaten will result from a limitation of admissions to the LTCH or satellite, we would once again respond that our policy does not limit patient admissions, it sets appropriate payment for patient categories. Moreover, while we understand the concerns about the availability of intensive care unit beds in an acute care hospital, we believe that this is a problem that may occur due to other unexpected circumstances, for example, issues related to the need to appropriately staff those ICU beds. We do not believe that the

policy that we are finalizing would increase the possibility of this problem arising, particularly since it is generally clinically appropriate to move a patient no longer in need of ICU treatment to a "step-down" unit of the host acute care hospital and not to maintain the patient needlessly in an ICU bed.

In addition, as we explained earlier, for some patients in the acute care hospital, Medicare payment under the IPPS would include high-cost outlier payments. Under the policy described above, if an ICU patient had been moved to a "step-down" unit at the host hospital and the costs of treatment resulted in the case qualifying as a high cost outlier, Medicare payment for an admission of such a patient to the LTCH or satellite from the host acute care hospital would not be included as an admission from the host and would be paid based at the higher LTCH PPS rate. Accordingly, we believe with this policy we have addressed some of the concerns raised by the commenters as to the effect of the separateness percentage policy on access to services. We would also remind the commenters that we have established adjustments to the 25 percent test for rural hospitals or urban single or MSA dominant hospitals in response to situations where communities have a scarcity of inpatient options, thus further tailoring the revised policy to the unique needs of these communities.

Comment: Several commenters expressed concern with the impact of the proposed 25 percent test on rural hospitals.

Response: The Congress has authorized special treatment for rural areas under the Medicare program in a number of areas. In addition, we agree with the commenter that in rural areas it often will be difficult for a LTCH HwH or satellite not to exceed the

25 percent threshold since the co-located acute care hospital may be the only one in the area. To address this issue, as noted in the previous response, we are finalizing a modification of our 25 percent test for rural hospitals (and also for urban single or MSA-dominant hospitals). We would also note, however, that while we have addressed the commenters' concerns with LTCH HwHs in rural areas, in fact, there are very few rural LTCHs, even including free-standing LTCHs. With approximately 320 LTCHs in existence, the vast majority of rural areas throughout the country do not have either free-standing LTCHs or LTCH HwHs or satellites. Therefore, currently almost all patients in need of hospital-level long-stay care are being treated as high-cost outliers in rural acute care hospitals and are not treated in LTCHs.

Comment: Several commenters questioned CMS' authority to impose new criteria for exclusion of long-term care hospitals and contend that existing separateness and control rules already enables us to distinguish between hospitals and units. The commenters state that the sole reliance on the 25 percent test establishes "admissions criteria," and the Secretary does not have the right to disqualify a LTCH HwH or satellite meeting other exclusion criteria from payment under the LTCH PPS based on a failure to meet admissions criteria. The commenters stated that the term "hospital" is defined in section 1861(a) of the Act and that section 1886(d)(1)(B)(iv) of the Act provides an exclusion from the prospective payment systems for a hospital having an average length of stay greater than 25 days. These commenters therefore maintain that if a LTCH qualifies for Medicare participation by meeting the applicable participation requirements in 42 CFR Part 489 and also meets the statutory "greater than 25 day length of stay

criterion", CMS has no right to "remove" this status because of where the LTCH is located or because of the source of its admissions. Several commenters claim that the proposed policy is "arbitrary and capricious" and one commenter maintains that the regulations fail the "Chevron test."

Response: We do not agree that we have imposed additional criteria for the exclusion of LTCHs. Rather we are imposing new criteria for adjusting payments under the LTCH PPS for LTCH HwHs or satellites.

The commenters are correct in noting that the term "hospital" is defined in section 1861(e) of the Act and that a statutory definition of a LTCH is the one set forth in section 1886(d)(1)(B)(iv)(I) of the Act. However, this fact does not mean that the Secretary is precluded from acting, under the general rule-making authorization in sections 1102 and 1871 of the Act, to establish further rules and regulations as necessary to administer the Medicare program and to prevent exclusions or excessive payments that are contrary to the purpose of the statutory scheme. Section 123 of BBRA of 1999 as amended by section 307 (b) of BIPA of 2000 confers upon the Secretary tremendous discretion in creating the LTCH PPS. As explained in the preamble to the proposed rule published on May 18, 2004, we continue to be concerned that only qualified facilities be excluded from the IPPS and paid under the existing LTCH PPS and that payments under each system (IPPS and LTCH PPS) be made appropriately.

When we first established regulations for LTCH HwH, in the September 1, 1994 final rule for the IPPS, in §412.22(e), we stated that a LTCH HwH or satellite must "meet the following criteria in order to be excluded from the prospective payment systems

specified in §412.1(a)(1)." At that time, we explained in the preamble as follows: "[A]s discussed above and in the proposed rule, we are adding new criteria to prevent an inappropriate exclusion from the prospective payment system. The purpose of excluding entities from the prospective payment system is to address situations in which the principles of prospective payment do not apply well. The considerations underlying exclusions may not apply to situations involving a 'hospital within a hospital.' If an entity is effectively part of another hospital and the principles of prospective payment do apply well to the organization as a whole, then it would not be appropriate to exclude part of that organization from the prospective payment system. Moreover, we believe that granting an exclusion to a LTCH HwH or satellite may be contrary to the statutory scheme. The statute provides for exclusion of certain types of hospitals and certain types of hospital units. Significantly, the statute does not provide for exclusion of LTC units. A LTCH HwH or satellite may essentially be a long-term care unit of another hospital. We believe these distinctions are meaningful and that it would undermine the distinctions if we allowed exclusion of entities that are essentially long-term care units (59 FR 45390, September 1, 1994). "Thus, in order to prevent exclusions that are contrary to the purpose of the statutory scheme [section 1886(d)(1)(B) of the Act] we proposed additional criteria for entities seeking exclusion. Sections 1102 and 1871 of the Act confer authority on the Secretary to establish rules and regulations as may be necessary to administer the Medicare program." (59 FR 45390, September 1, 1994). Existing regulations, therefore, finalized in 1994 established the regulatory principle that in order

to be paid as a hospital excluded from the IPPS, separateness and control requirements would have to be met.

The 25 percent or other applicable percentage threshold test that we are finalizing in this document in new §412.534 does not remove LTCH status from a hospital that otherwise meets these separateness and control requirements, as the commenter suggests. In fact, we are defining a level of payment distinction based upon an adjustment that, following the 4-year phase-in, will enable an existing hospital or satellite or new HwHs effective with cost reporting periods beginning on or after October 1, 2004, to retain its excluded status but to be paid under an otherwise unadjusted LTCH PPS payment for up to 25 percent (or the adjusted threshold established for rural, urban single, or MSA dominant hospitals) of its discharged patients that are admitted to the LTCH HwHs or satellites from the host hospital. If the LTCH or satellite exceeds this 25 percent (or the applicable percentage) threshold, Medicare payments under the LTCH PPS will be based on the lesser of an otherwise unadjusted LTCH PPS payment for the case or an amount equivalent to what would have otherwise been paid for that case under the IPPS. We would note that this policy merely represents a new adjustment in the evolution of the LTCH PPS. We believe that LTCH HwHs that discharge greater than the appropriate percentage of patients admitted from their hosts may be understood to be functioning as units and therefore, we believe that it is appropriate to adjust the payment to be made to the LTCH under the LTCH PPS. The payment adjustment we are implementing is not the equivalent to setting "admissions criteria" for treatment at a LTCH. As noted elsewhere in these responses, a LTCH is free to admit as many patients as it can safely

treat and from whatever source(s) it chooses. The policy revision that we are finalizing in this document establishes a payment formula that will enable the LTCH to be paid under the LTCH PPS appropriately for patients admitted to the LTCH from other than the host and appropriately for patients admitted to the LTCH HwH or satellite from the host where the LTCH has exceeded the applicable threshold, albeit at different LTCH PPS rates. We want to emphasize that the medical and administrative governance component of the separateness and control criteria at §412.22(e)(1) through (e)(4) will continue to apply to LTCH HwH or satellite but, as explained in detail above, we are deleting paragraph (e)(5), the performance of basic hospital functions test to LTCHs as a basis for determining whether they may be paid as an IPPS-exempt hospital. Rather the 25 percent or other applicable percentage criterion will be used as a basis for a payment adjustment under the LTCH PPS.

We believe that the regulations that we are finalizing represent a permissible construction of the statute precluding the establishment of LTCH units at section 1886(d)(1)(B) of the Act, and are consistent with sections 1102 and 1871 of the Act which confer authority on the Secretary to establish rules and regulations as may be necessary to administer the Medicare program. It is also consistent with our statutory authority under section 123 of BBRA as amended by section 307(b) of BIPA. Moreover, they are consistent with the statute and the statutory scheme. The finalized payment policies described below and the concerns that they represent echo concerns first expressed in the September 1, 1994 final rule for the IPPS, when we began to regulate

new entities that we named 'hospitals within hospitals' and after ten years, represent a reasonable extension of existing regulatory policies.

Comment: We received several comments that asserted that in establishing the category of hospitals excluded from the IPPS, the Congress recognized that the DRG payment system did not accurately reflect the patient census and types of treatment found in those hospitals. These commenters also quoted the requirements of the BBRA and BIPA for the establishment of a specific PPS for LTCHs "reflecting differences in patient resource use" and that therefore paying a LTCH under the IPPS, as we described in our third payment option in the proposed rule, would constitute a statutory violation.

Response: In the proposed rule, we expressed this payment scheme incorrectly when we described payment as "the lesser of the IPPS payment or the LTCH PPS payment." The payment formula, as we described in a previous response, is not, in fact, an IPPS payment at all but instead is an adjusted payment under the LTCH PPS. In section 307(b) of Pub. L. 106-554, the Congress conferred broad authority on the Secretary to include "appropriate adjustments" in the establishment of a PPS for LTCHs. As stated in previous responses, we are providing an adjustment to Medicare payments under the LTCH PPS in the event that a LTCH HwH or satellite LTCH admits a greater number of patients from its host above the 25 percent or other applicable percentage threshold. This adjustment to the LTCH PPS would allow, for each additional case that the LTCH admitted that were discharges from the host, beyond 25 percent (or the applicable percentage), a payment that would be based on the lesser of an amount payable under this subpart that is equivalent to what would have otherwise been paid

under the IPPS or the otherwise payable LTCH PPS payment amount. We believe that this specific adjustment to payments under the LTCH PPS is comparable to other adjustments that we established under the LTCH PPS, such as the short-stay outlier policy (§412. 529) and both the 3-day or less and the greater than 3-day interruption of stay policy (§412.531), in that we have attempted to adjust the otherwise payable LTCH PPS payment rate to more accurately pay for a specific type of patient stay. If a patient stay is governed under any one of these policies, payment under the LTCH PPS will be computed differently than it would for a typical LTCH stay where the patient remains in the LTCH for greater than 5/6 of the average length of stay for the applicable LTC-DRG to which the episode is grouped. We believe that paying the LTCH an LTCH PPS adjusted payment that is the lesser of the LTCH PPS payment amount or a payment equivalent to the amount that would have otherwise been made under the IPPS, when a particular LTCH exceeds the percentage of admissions established under the formula set forth above, is entirely compatible with the broad statutory authority conferred on the Secretary, in section 307 of the BIPA, to establish a LTCH PPS and provide for "appropriate payment adjustments" under that system.

Comment: We received six comments on the grandfathering of existing host/LTCH HwH arrangements where the LTCH HwH had in the past met the 15 percent test for purposes of demonstrating compliance with the performance of basic hospital functions requirements. Four commenters urged us not to finalize the proposed revisions to the separateness and control policies but, as an alternative, to grandfather all existing LTCH HwHs and hence exempt them from prospective compliance with new finalized

regulations until "an in-depth study of the industry has been completed or until alternative qualifying criteria are implemented." One commenter opposed any grandfathering provision, absent a statutory approval, stating that such a policy provided no benefit for Medicare patients or the Medicare program and could serve to institutionalize behavior that we had already determined was in contravention of the intent of LTCH HwH regulations. Two commenters specifically suggested that we permit entities to unwind abusive practices within a specific period of time rather than legitimize abuses through grandfathering. Two commenters expressed concern about including providers that are in the formative stages any grandfathering protection. One commenter specifically urged us to include hospitals that were in their 6-month qualification period for LTCH classification and would be in compliance by January 1, 2005 and to deem them to meet existing governance, separateness and control policies and therefore to be eligible for any grandfathering provision that we would finalize. These commenters suggest that we establish a provision similar to that in section 507 of Pub. L. 108-173 that established a moratorium on physician-referrals to specialty hospitals in which they have an ownership or investment interest but grandfathered in those facilities under development. Without such a provision, the commenters believe that the financial backers (the host hospital in partnership with a venture capital group) would lose a considerable investment of time and resources.

Response: As noted in a previous response, the LTCH HwH or satellite policy that we are finalizing to ease the transition to the new policy for existing LTCH HwHs and satellites, we specify a 1-year grandfathering for LTCH HwHs or satellites that had

been paid under the LTCH PPS as of October 1, 2004 and also for LTCH HwHs-in-formation that qualify under the following two-pronged test: they were certified as acute care hospitals, under Part 489, on or before October 1, 2004; and they achieved LTCH designation prior to October 1, 2005. This two-pronged test identifies hospitals that by the effective date of this regulation, have been operating in anticipation of becoming a HwH under the existing rules.

The finalized policy provides for an adjusted payment for LTCH HwHs and satellites that admit more than 25 percent of their patients (with an adjusted percentage for rural and urban single or dominant hospitals) effective for cost reporting periods beginning on or after October 1, 2004. Further, for both existing LTCH HwH and LTCH satellites and those LTCHs-in-formation that meet the above tests, following the 1-year hold-harmless provision, we have provided a 3-year transition, in order to allow LTCH HwHs or satellites and their hosts what we believe is sufficient time to adapt to the new requirements and enable them to ultimately meet the 25 percent or other applicable percentage test. We believe that establishing this provision is a fair and equitable response to concerns expressed by providers, members of the Congress who have written on behalf of their constituent LTCHs, and LTCH trade groups.

The LTCH PPS, from its inception, has included an evaluation and monitoring component which focuses on the LTCH industry and in light of policy recommendations made by MedPAC in its June 2004 Report to the Congress, we plan to expand these initiatives. However, we do not believe that it would be appropriate to delay implementing these payment policies affecting LTCH HwHs or satellites pending the

results of such on-going analysis. We also see no need to adopt a policy that would allow time for entities to correct prohibited practices prior to the imposition of sanctions since we are eliminating the necessity to comply with the performance of basic hospital functions requirements under §412.22(e)(5) and rather relying on changes to the payment policy to address situations where a LTCH HwH or satellite exceeds the percentage threshold of patients admitted from the host, effective with cost reporting periods beginning on or after October 1, 2004. With the October 1, 2004 implementation of this final rule, for LTCHs that are not grandfathered, we will rely on the 25 percent test as a basis for a payment adjustment under the LTCH PPS at new §412.534, if a LTCH HwH complies with the medical and administrative separateness and control requirements of §412.22(e)(1) through (e)(4) or the LTCH-in-formation meets the LTCH HwH requirements prior to October 1, 2005 and the satellite meets the requirements at §412.22(h). We also do not believe the statutory protection for those facilities under development promulgated by in the moratorium on physician-owned specialty hospitals established under section 507 of the Pub. L. 108-173 is applicable to this provision.

Comment: We received numerous comments urging us not to finalize the proposed policies that would prevent admissions to LTCH HwHs or satellites from being based on determinations of medical necessity, clinical assessment, and treatment practices, but rather, based on a restrictive numerical admission standard. Comments from industry groups, members of the Congress, host hospitals, LTCH HwHs or satellites, and physicians practicing at these providers, and in communities where they are located, objected to the proposed elimination of other options for qualification as a LTCH

and instead, requiring LTCH HwHs or satellites to comply with the 25 percent test. The commenters believe this change in policy will have a significant impact on physician decision-making and admission policies at LTCH HwH or satellite. Several physicians accused us of being disingenuous in drawing a sharp distinction between payment policy and its impact on medical decision-making.

Response: We disagree with the commenters' assertion that finalizing our 25 percent or other applicable percentage test for determining payments to LTCH HwH or satellite will interfere with a physician's efforts to procure the highest level of medical care for Medicare beneficiaries. Once again, we must state that we are not preventing the admission of patients to the LTCH HwH or satellite; rather we are establishing a methodology for determining what are fair and reasonable payments based on the type of patient being treated at the LTCH HwH or satellite. We continue to believe that there is a clear distinction between medical decision-making and payment policy, particularly on the physician level, when the patient is a Medicare beneficiary and the medically necessary services are covered by Medicare.

There has always been a range of payments under Medicare for services that, from a medical standpoint, could appear to be identical. Since its inception, the LTCH PPS has included patient-level adjustments to the per discharge Federal payment rate, whereby Medicare would adjust payments depending upon the patient's length of stay, or whether the patient was being readmitted to the LTCH following a brief stay for treatment in another setting, or from a co-located provider. Similarly, in general, under Medicare's PPSs for inpatient services there have always been facility-level adjustments

for variables including size and location of the hospital, presence of training programs, or the nature of the population served. Thus, payment for a patient at one facility could differ considerably from payment for a patient with similar clinical needs at another facility. Additionally, acute care hospitals, rehabilitation hospitals, and LTCHs can often be a legitimate site of care provided to a specific patient. However, Medicare's distinct PPSs for each of these provider types would provide for different payments to the specific hospital that treated the patient based upon the provider category. This is another example that demonstrates that under Medicare, payments for the same diagnosis, even for the same patient, could vary depending upon where the patient was admitted. Even within the same facility, a different Medicare payment would be made under the acute hospital IPPS for a rehabilitation or a psychiatric DRG than would be made for the same diagnosis if the patient is admitted to the IPPS-excluded rehabilitation or psychiatric unit at that hospital. We do not agree that in setting payment policy we are restraining physicians from utilizing their best clinical judgment on behalf of their patients. We continue to believe that payments made under the policy that we are finalizing in this document simply represent another patient-level adjustment under the LTCH PPS.

Comment: We received numerous comments from LTCHs, industry groups, Congressional representatives, and individual medical professionals expressing great concern that the proposed policy, which required compliance with the 25 percent test, would have very deleterious consequences for Medicare beneficiaries. The commenters asserted that the policy would establish new admissions criteria and, in effect, act as a quota or cap on patient admissions to LTCH HwHs eliminating beneficiary and family

choice as to treatment settings, produce needless trauma for beneficiaries, and reduce beneficiary access to the level of quality care that such settings could provide. Several commenters state that our proposed policies would violate sections 1801 which, among other matters, preclude any Federal officer or employee from interfering in the practice of medicine or the provision of services; and section 1802 of the Act, which they interpret to mean that Medicare beneficiaries cannot be denied health services. The commenters believe that LTCHs forced to monitor admissions from the host will have a strong incentive to deny patients medically necessary inpatient service as the percentage of admissions from the host approaches 25 percent. Three commenters emphasized that there would be less likelihood of medical errors if a patient discharged from an acute care hospital could be admitted to an onsite co-located facility because of consistency in care and "fewer handoffs" would decrease the possibility of errors occurring. The costs of care would also be reduced because it would be unnecessary to repeat tests and other ordered procedures. Furthermore, the commenters felt that proposing such a policy indicated a lack of appreciation for the specialized care provided by LTCH HwHs and LTCHs in general.

Response: We disagree with the commenters who assert that through finalizing the 25 percent (or the applicable percentage) criterion, as a basis for adjusting payments to LTCH HwHs or satellites for patients admitted to the LTCH from the host acute care hospital, we are restricting patient care. As stated in the previous responses, we have established a payment policy, not a patient care policy. We would remind commenters who express disapproval of a LTCH monitoring its admission numbers as it approaches

its threshold, that even before the October 1, 2002 implementation of the LTCH PPS, LTCHs under the TEFRA system had to monitor their admissions as well as their lengths of stay lest they fall below the greater than 25 day average length of stay qualification threshold for designation as a LTCH. From our research in designing the short-stay outlier policy during the development of the LTCH PPS, we became distinctly aware of admission choices made by LTCHs, particularly as the cost reporting period was drawing to a close, if the length of stay averages were below the greater than the 25 day threshold required by the statute. Thus, this phenomenon is neither unique nor new. The establishment of a payment policy that may result in payment adjustments for certain admissions is well within the existing regulatory framework. We fail to see the relationship between the payment policy we are finalizing and an increase in the likelihood of medical errors, unnecessary tests, or other ordered procedures, patient trauma, or disruption in the consistency of care. Nor do we see compliance with the policy as leading to increased costs. We are finalizing this policy because we are concerned that the co-location of an acute hospital and a LTCH with significant patient movement from the acute hospital to the LTCH may violate the intent of the prohibition of LTCH units under section 1886(d)(1)(B) of the Act, a prohibition that was established in order to protect the Medicare system against unnecessary and inappropriate payments. We are finalizing a payment policy premised upon the fact that LTCH HwHs or satellites that admit more than a specified percentage of patients from their hosts are functioning as units and we are adjusting payments to the LTCH HwH or satellite accordingly. However, as explained earlier, we have revised the policy as proposed to reflect unique

location factors and we allow for full payments beyond the threshold if the transferred patient has reached outlier status at the acute hospital. In this final rule, we have also provided for grandfathering of existing LTCH HwHs or satellites and certain LTCH HwHs that will be designated as LTCHs prior to October 1, 2005 and an additional 3-year phase-in to full compliance requirements. In these revisions, we have attempted to respond to valid concerns raised by our commenters as well as maintain the integrity of the statutory scheme in section 1886(d)(1)(B) of the Act which precludes LTCH units. Although we strongly disagree that our payment policy will have the effect of restricting patient care at LTCH HwHs or satellites, we will respond to the commenters regarding the sections of the Act that they believe we are violating. As explained above, we do not believe that this policy interferes with the practice of medicine or provision of health care services under section 1801 of the Act. The policies that we are finalizing, as we explained earlier, are merely payment provisions. Nor are we violating section 1802 of the Act by interfering with a beneficiary's right to total self-determination regarding health care. This interpretation of the provision is incorrect. The statute actually says, "Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency or person qualified to participate under this title <u>if such institution, agency, or person undertakes to provide him such service.</u>" (emphasis added) In addition, our finalized rules do not preclude a beneficiary from seeking admission to a hospital of his or her choice. We continue to believe that we have not promulgated rules that will prohibit a LTCH from providing necessary services to Medicare patients, even if they are patients that are admitted from the co-located host hospital. Our LTCH HwH

and satellite rules do not prohibit a hospital from admitting a patient. Rather, our LTCH HwH and satellite rules are payment rules that set forth how a LTCH HwH or satellite will be paid under a particular set of circumstances.

Comment: We received a comment from MedPAC that brought the following points to our attention: (1) the rapid growth in LTCH HwHs and rapid increases in Medicare spending for LTCH services; (2) the existence of a LTCH HwH quadrupled the probability that a beneficiary would use LTCH care; (3) freestanding LTCHs also have strong relationships with acute care hospitals, and that where on average LTCH HwHs receive 61 percent of their patients from their hosts, freestanding LTCHs receive 42 percent from their a primary referring hospital; (4) concerns with LTCHs may be related to the payment systems and CMS policies for SNFs and acute care hospitals and should not therefore be considered in isolation; (5) there are some risks in CMS's proposed 25 percent policy; a) the 25 percent rule that only applies to LTCH HwHs and not to freestanding LTCHs and may therefore be inequitable; (b) it does not ensure that patients go to the most appropriate post-acute setting; (c) this approach may be circumvented by an increase in the number of freestanding LTCHs instead of LTCH HwH. MedPAC shares our concern that the LTCH payment system creates an incentive for unbundling of the IPPS in addition to overpayment for the care provided by LTCHs and that this concern is great, particularly, in the case of a LTCH HwH.. In MedPAC deliberations, the Commission considered recommending a moratorium on LTCH HwHs but did not adopt it. Finally, MedPAC stated that it reserves judgment on our proposed policies for

LTCH HwHs pending more empirical evidence demonstrating the unique risk posed by them.

Response: We appreciate the comments from MedPAC, which are consistent with our strong concerns with the growth in the number of LTCH HwH and our continuing questions about the relationships between treatment at acute care hospitals and LTCHs, as well as the linkage between payment policies and substitution of services especially among acute care hospitals, LTCHs, and some SNFs. While we also understand the reservations expressed in the comments, we want to emphasize that, as explained earlier, we are establishing these revised payment policies in this final notice for LTCH HwHs or satellites and not freestanding LTCHs because of the considerable growth in the number of LTCH HwH and because, ever since we first became aware of the existence of LTCH HwHs in 1994, we have been mindful of the strong resemblance that they bore to LTCH units of acute care hospitals, a configuration precluded by statute. The proposed policies are not intended to ensure that patients go to "the most appropriate post-acute setting." Rather, we believe that it is incumbent upon us to continually refine our payment systems to maintain the continued viability of the Medicare Trust Fund. In finalizing the revised LTCH HwH policy, therefore, as discussed previously in this preamble, we believe that this policy will help to protect the integrity of the IPPS DRG system as well as discouraging inappropriate payments under the LTCH PPS, the system that provides for the highest per discharge payment to a provider in the Medicare program. These policy goals typically require both proactive as well as reactive decisions on our part. We strongly support MedPAC's approach in their recent recommendations

for developing standards that would identify the unique characteristics of a LTCH that warrant increased payments under the LTCH PPS. It is also important, as recommended by MedPAC to identify the specific types of patients that should be the unique patient load of LTCHs. Prior to the end of the 4 year transition period, CMS will reevaluate the HwHs criteria to assess the feasibility of developing facility and clinical criteria for determining the appropriate facilities and patients to be paid for under the Medicare LTCH PPS. If, during that time period, data from well-designed studies (or other compelling clinical evidence) indicate that developing this criteria is feasible, we would consider revisions to the HwH regulations. We intend to analyze these issues and discuss any findings in the forthcoming FY 2006 LTCH PPS notice.

Comment: Several commenters allege that the proposed requirement for compliance with the 25 percent test will undermine two existing requirements of the Medicare program: discharge planning and the involvement of the Quality Improvement Organizations (QIOs). Regarding discharge planning, the commenters argue that the 25 percent test will impact the host hospitals' requirement for discharge planning by limiting the most obvious site for continued treatment, which would be the onsite LTCH, and they believe that our proposed policy will encroach upon the responsibility of the QIOs to determine whether or not a case meets the standard of medical necessity.

Response: We do not agree with the commenters that the proposed policies in any way undermine the discharge planning function at the acute care hospital, set forth in §482.43, or affect the involvement of QIOs in medical review at §412.508. First of all, we must assert that the 25 percent test (which as a result of the changes in this final

notice, for some hospitals, will actually be higher than 25 percent) does not set a cap or quota on the number of patients from the host hospital that the LTCH is permitted to admit. We are establishing payment policy based on a policy rationale first established in the September 1, 1994 final rule for the IPPS (59 FR 45390) wherein we stated that "the extent to which a facility accepts patients from outside sources can be an important indicator of its status as a separate facility, not merely a unit of another hospital." As noted elsewhere in these responses, we have revised existing regulations to specify a new standard solely for the purpose of determining appropriate Medicare payments. Accordingly, the finalized policy is a change only to payment policy and should not directly impact discharge planning. Under §482.43 "…[a] hospital must have in effect a discharge planning process that applies to all patients." Paragraph (b)(3) of this regulation specifies that "[T]he discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services." (emphasis added.) Although we expect that the financial implications of the payment policy adjustments that we are finalizing may be factored into determinations of whether or not a particular post-acute provider is willing to admit a specific patient, there are additional factors that could typically affect the "availability of services" (that is, the decision by the post-acute provider about whether to admit the patient in question). These factors include available bed space or ongoing compliance with regulations specific to each provider-type, such as the need for a LTCH to annually meet its greater than 25-day average length of stay requirements. Therefore, in light of the factors that must be considered by a post-acute hospital, we believe that rather than undermining the

discharge planning process, the payment policy for LTCH HwHs or satellites that we are finalizing in this notice may join other issues that generally would be evaluated prior to accepting a patient from another hospital.

In response to the commenters' assertions that our proposed regulations undermine the role of QIOs as a vehicle to identify and prevent inappropriate utilization of LTCH HwHs or satellites, we note that, despite the importance of QIO activities in specific case review, and identification of treatment trends, we do not believe that, at least presently, the involvement of QIOs would be effective in dealing with problems of inappropriate payments for patients admitted to the LTCH HwH or satellite from the host hospital since so few discharges are actually subjected to QIO review.

Comment: We received a comment from an organization representing fiscal intermediaries requesting further information on implementation procedures should the proposed policies be finalized. In particular, there were questions about implementing on a systems level any of the three options proposed under the proposed 25 percent rule. The commenter suggests that we base payments for LTCH HwHs on one methodology for all Medicare patients, regardless of source of referral and therefore supports the option by which if the percentage of patients that a LTCH receives from its acute care hospital host exceeds 25 percent that the LTCH will no longer be paid as an excluded hospital. Another comment from an industry association urged us to subject any procedure by which a fiscal intermediary would evaluate compliance with a 25 percent test to public comment, because the commenter believes that our "…proposals are too vague and complicated for public comment at this time."

Response: Although we understand that establishing a "bright-line" policy whereby if hospitals fail the 25 percent (or the applicable percentage) test they would not be paid as excluded hospitals, is technically less complicated for fiscal intermediaries, we believe that the policy that we have established appropriately addresses our policy concerns and is also equitable to those LTCHs that exist as LTCH HwHs or satellites and their host hospitals. We further believe that as discussed earlier in this preamble, there are ample systems-wide precedents (for example, transfer policy under the IPPS) for the type of policy adjustments that we are finalizing. Finally, the systems procedures that we establish in order to implement our policies are communicated in program memoranda that we will issue to our fiscal intermediaries following the October 1 effective date of the final rule and are not subject to notice and comment rule-making.

Comment: The majority of those commenters who disagreed with any of the specifics of our proposed policies for HwHs acknowledged our concerns about the unprecedented growth in the number of LTCH HwHs and the potential for inappropriate discharging of Medicare patients from the host hospitals to the LTCH HwH. Several commenters commended us for our "efforts to identify systemic abuses and to make policy changes that will result in cost savings." A number of commenters believe that our concern goes back to the broader issue which is that, presently, there is no clear and enforceable definition of LTCHs on a facility level and there are no appropriate medical standards for patient admission or retention. Moreover, there is no established criteria for what would constitute an appropriate discharge pattern from an acute care hospital to an on-site LTCH. Three commenters claim that our proposed policy does not address

underlying issues of payment for an inappropriate level of care. There was significant concurrence among the majority of commenters, regardless of the degree to which they either endorsed or disagreed with our proposed policies, that we should study admission, discharge, and treatment patterns between acute care hospitals and all LTCHs, co-located or free-standing, and establish facility-level and patient criteria that could lead to criteria for "certification" as recommended by MedPAC in its June 2004 Report to the Congress. (Several commenters noted that one LTCH industry group has established a set of admission standards already being used by its member LTCHs.) Two commenters further encouraged us to establish a workgroup in collaboration with the Congress, providers, industry groups, and other interested parties to explore these issues.

Response: We thank the commenters for agreeing with our concerns regarding the unprecedented growth in the number of LTCH HwHs the potential for inappropriate patient shifting between host hospitals and LTCH HwHs, and significantly, our efforts to identify abuses that threaten the viability of the Medicare Trust Fund. We agree with commenters that it may be worthwhile to examine patient and facility issues. Further examining of these issues may be beneficial in establishing the most effective and cost-efficient utilization of LTCHs and in assuring that Medicare beneficiaries receive the appropriate level of treatment and care in that setting. We continue to believe, however, that the policies that we have revised in this final notice are an appropriate response to concerns about Medicare payments to host hospitals and LTCH HwHs or satellites expressed throughout this preamble.

We also endorse the widespread enthusiastic industry support garnered by the recommendations in MedPAC's June 2004 Report to the Congress on "Defining long-term care hospitals." Although we continue to believe that the policy revisions regarding payments for patients from host hospitals to LTCH HwHs or satellites are necessary and appropriate to address the immediate problem we have identified with LTCH HwHs or satellites, which is underscored by the recent growth in those facilities, we believe that MedPAC has definitely identified the most significant issues for Medicare regarding payment policy for LTCHs, in general. We intend to address MedPAC's suggestions in a more thorough evaluation and discussion of the issues MedPAC has raised, in future Federal Register publications updating the next year's LTCH PPS. We further believe that MedPAC's June 2004 Report to the Congress has made a substantial contribution to a frank and fair exchange on issues dealing with payments to LTCHs. We wish to commend the Commission on a level of analysis that helped focus CMS on the growth in LTCH HwHs.

We are also aware that versions of admission criteria for LTCHs have been produced and have heard that some LTCHs have begun to use them. In response to the two commenters who urged us to convene a workgroup made up of providers, industry groups, and the Congress, we value our frequent contacts with all of these groups and will determine whether we will convene this group in the future.

We are finalizing revisions to separateness and control regulations at §412.22(e) and adding new regulation at §412.534, Special payment provisions for long-term care hospitals within hospitals.

Effective for cost reporting periods beginning on or after October 1, 2004, we are limiting the finalized policy revisions to addressing LTCH HwHs and also satellites of LTCHs (either LTCH HwH or free-standing). The policies will also be applicable for any type of host, including an IRF. We are finalizing policy to eliminate the existing three "Performance of basic hospital functions" options under existing §412.22(e)(5) for qualifying as a LTCH HwH (the 15 percent rule and the basic functions test, and the 75/25 test). If a LTCH HwH meets existing separateness and control of administrative and medical governance provisions at §412.22(e)(1) through (e)(4), payment will be made under the LTCH PPS as specified in §412.534. Under §412.534, if a LTCHs or satellite's discharges admitted from its host hospital exceed 25 percent (or the applicable percentage) of its discharges for the LTCH HwHs or satellite's cost reporting period, an adjusted payment will be made of the lesser of the otherwise full payment under the LTCH PPS and an amount that would be equivalent to what Medicare would otherwise pay under the IPPS. In determining whether a hospital meets this percent test, patients transferred from the host hospital that have already qualified for outlier payments at the host would not count as part of the host 25 percent (or the applicable percentage) and the payment for those patients would also not be subject to the adjustment. Those patients would be eligible for full payment under the LTCH PPS. (Discharges admitted from the host before the LTCH crosses the 25 percent (or the applicable percentage) threshold would be paid without the adjustment under the LTCH PPS.)

We are also finalizing additional adjustments to the 25 percent policy for specific circumstances. For rural acute care hospitals with LTCH HwHs or satellites, instead of

the 25 percent criterion, the majority, (that is, 50 percent or more) of the discharges would have to be from the hospitals other than the host. In addition, in determining the percentage of discharges admitted from the host, any patient that had been a Medicare outlier at the host and then admitted to the LTCH HwH or satellite would be considered as if they were admitted from a non-host hospital. For urban single or MSA dominant hospitals, we would allow the LTCH HwH or satellite to discharge patients admitted from the host up to the host's percentage of total Medicare discharges in the MSA for like hospitals. We would apply a floor of 25 percent and a ceiling of more than 50 percent to this variation. In addition, in determining the percentage of patients admitted from the host, any patient that had been Medicare outliers at the host and then admitted to the LTCH HwH or satellite would be considered as if they were admitted from a non-host hospital.

We are finalizing a 4-year phase-in of this policy for existing LTCH HwHs and satellites and also for LTCHs-under-formation that satisfy the following two-prong requirement: on or before October 1, 2004 they have certification as acute care hospitals, under Part 489; and before October 1, 2005 designation as a LTCH. For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005 these hospitals will be grandfathered, with the first year as a "hold harmless" followed by a percentage transition over the 3 years beginning in FY 2006. Grandfathered LTCH HwHs will need to continue to meet the existing separateness criteria at §412.22(e) which includes compliance with either paragraph (e)(5)(i), (ii), or (iii) for that first cost reporting period. We are requiring that even for grandfathered facilities, for cost reporting periods

beginning on or after October 1, 2004 and before October 1, 2005, the percentage of discharges admitted from the host hospital may not exceed the percentage of discharges admitted from the host hospital in its FY 2004 cost reporting period, which we have chosen since we are implementing the revised policy for cost reporting periods beginning on or after October 1, 2004 (FY 2005). We are establishing a transition percentage threshold for the percentage of discharges that may be admitted from the host before the payment adjustment applies to the discharge that were admitted from the host in excess of the threshold. After the first grandfathered cost reporting period, these LTCH HwHs and satellites will be required to meet a percentage transition over the 3 years beginning in FY2006. For the second year (cost reporting periods beginning on or after October 1, 2005, but before October 1, 2006) the percentage of the threshold will be the lesser of the percentage of their admissions from their host for their cost reporting period beginning on or after October 1, 2003 or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006, but before October 1, 2007), the percentage of the threshold will be the lesser of the percentage of their discharges admitted from their host for their cost reporting period beginning on or after October 1, 2003 or 50 percent, and for cost reporting periods beginning on or after October 1, 2007, the percentage threshold will be 25 percent or the applicable percentage.

Technical Change. In §412.22(e) of our regulations, we refer to a hospital-within-a-hospital as a hospital that "occupies space in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital" (emphasis added). The reference to "entire"

buildings is incorrect. We should have referred to "separate" buildings. Therefore, in the May 18, 2004 proposed rule, we proposed to correct this error.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs, under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation in 42 CFR Part 485, Subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR Part 413.

2. Payment Amounts for CAH Services (Section 405(a) of Pub. L. 108-173 and §§413.70 and 413.114 of the Regulations)

Prior to the enactment of Pub. L. 108-173, section 1814(l) of the Act provides that the Medicare payment amount for inpatient services furnished by a CAH is the reasonable costs of the CAH in providing the services. Section 1834(g)(1) of the Act provides that the Medicare amount of payment for outpatient services furnished by a CAH is also made on a reasonable cost basis, unless the CAH makes an election, under section 1834(g) of the Act, to receive a payment amount that is the sum of the reasonable cost of hospital outpatient facility services plus 115 percent of the amount otherwise paid for professional services. Section 1883(a)(3) of the Act provides for payment to a CAH for covered skilled nursing facility services furnished under an agreement entered into under section 1883 of the Act on the basis of the reasonable costs of such services.

Regulations implementing these provisions are set forth in §413.70(a), for inpatient CAH services; in §413.70(b), for payment under the standard method for the reasonable costs of facility services, and outpatient CAH services; in §413.70(b)(3), for the optional method of payment for outpatient services (reasonable costs for facility services plus fee schedule for professional services); and in §413.114, for SNF services of a CAH with a swing-bed agreement.

Section 405(a) of Pub. L. 108-173 amended sections 1814(l), 1834(g)(1), and 1883(a)(3) of the Act to provide that, effective for services furnished during cost reporting periods beginning on or after January 1, 2004, the amount of the payment for inpatient, outpatient, and SNF services, respectively, furnished by a CAH is equal to 101 percent of the reasonable cost of the CAH in providing these services.

In the May 18, 2004 proposed rule (69 FR 28327-28328), we proposed to revise §§413.70(a)(1), (b)(2), and (b)(3) and §413.114 of our regulations to incorporate the change in the payment percentage made by section 405(a) of Pub. L. 180-173. We also proposed to make a technical correction to §413.70(b)(2)(i) to remove paragraphs (b)(2)(i)(C) and (D). We proposed to delete these paragraphs to conform the regulations to provisions of the outpatient hospital PPS.

We note that in the IPPS final rule published in the **Federal Register** on August 1, 2001 (66 FR 39936), we added a new paragraph (a)(1)(iv) to §413.70. However, when the change was incorporated into the Code of Federal Regulations, paragraphs (a)(1)(i), (a)(1)(ii), and (a)(1)(iii) were inadvertently omitted. Our proposed revision of §413.70(a)(1) would correct the omission of these three paragraphs.

We did not receive any public comments on our proposals. Accordingly, in this final rule, we are adopting the proposals as final without modification.

3. Condition for Application of Special Professional Service Payment Adjustment (Section 405(d) of Pub. L. 108-173 and §413.70(b) of the Regulations)

As stated earlier, section 1834(g) of the Act provides for two methods of payment for outpatient CAH services. Under the provisions of section 1834(g) of the Act, a CAH will be paid under a reasonable cost method unless it elects payment under an optional method. Under the reasonable cost payment method, facility services are paid on a reasonable cost payment basis by the fiscal intermediary to the CAH, and physician and other professional services to CAH outpatients are paid for under the physician fee schedule, with payments being made by the carrier. Under the optional method (frequently referred to as "method 2"), CAHs submit bills for both facility and professional services to the fiscal intermediary. If a CAH elects the optional method of billing for outpatient services, Medicare payment for its facility services are made at the same level as would apply under the reasonable cost reimbursement method, but services of professionals to outpatients are paid for at 115 percent of the amounts that would otherwise be paid for under the physician fee schedule. To make the optional method election feasible and to help prevent possible duplicate billing, we require practitioners furnishing services to outpatients of a CAH to agree to reassign to the CAH their rights to bill the Medicare program for those services.

Existing regulations at §413.70 (b) set forth these payment options and specify that an election of the optional method, once made for a cost reporting period, remains in

effect for all of that period and applies to all services furnished to CAH outpatients during that period. This means that, under existing regulations, a CAH may elect the optional method payment only if all of its practitioners agree to reassign their billing rights for outpatient services to the CAH.

Section 405(d)(1) of Pub. L. 108-173 amended section 1834(g)(2) of the Act by adding a sentence after paragraph (B) to specify that the Secretary may not require, as a condition for a CAH to make an election of the optional method of payment, that each physician or other practitioner providing professional services in the CAH must assign billing rights with respect to the services. However, the optional payment method does not apply to those physicians and practitioners who have not assigned such billing rights. In other words, section 405(d) of Pub. L. 108-173 amended the Medicare law to authorize CAHs to elect the optional payment method even if some practitioners do not reassign to the CAH their rights to bill for professional services to CAH outpatients. However, it also specifies that the 15-percent increase in payment for those services is not available for professional services for which billing rights are not reassigned to the CAH.

The provisions of section 405(d)(1) of Pub. L. 108-173 are effective for cost reporting periods beginning on or after July 1, 2004. However, section 405(d)(2)(B) of Pub. L. 108-173 also states, in a special rule of application, that in the case of a CAH that made an election before November 1, 2003, the provisions of section 405(d)(1) of Pub. L. 108-173 are effective for cost reporting periods beginning on or after July 1, 2001.

Consistent with section 405(d)(2)(B) of Pub. L. 108-173, we do not intend to attempt recovery of certain amounts paid improperly in the past to CAHs for professional services that the CAHs billed under the optional payment method, even though the CAHs had not obtained reassignments of billing rights from all physicians and other practitioners furnishing professional services to their outpatients, as required by §413.70 as in effect at that time. However, in the May 18, 2004 proposed rule (69 FR 28328), we proposed to clarify that the special rule of application in section 405(d)(2)(B) of Pub. L. 108-173 is not to be interpreted to permit a CAH to obtain payment under the optional payment method for any cost reporting period based on an election made for a prior period or on an optional payment method election that was withdrawn or revoked prior to the start of the cost reporting period for which it was made.

To illustrate the application of section 405(d)(2)(B) of Pub. L. 108-173, assume that on October 1, 2002, a CAH elected method 2 for its cost reporting period starting on January 1, 2003, but did not obtain reassignments from all physicians treating its outpatients, as required by regulations in effect at that time. Under section 405(d)(2)(B) of Pub. L. 108-173, CMS would not recover any amounts from the CAH for payments for services furnished during that cost reporting period (January 1, 2003, through December 31, 2004) that are attributable to that election, even though the election was inappropriate based on the regulations that were in effect at the time it was made. Assume further that the same CAH recognized its error and did not make a method 2 election for its cost reporting period beginning January 1, 2004, thus receiving payment under method 1. The fact that the election of October 1, 2002, was made prior to

November 1, 2003, is not material in this case and cannot be interpreted to justify method 2 payment for the cost reporting period beginning January 1, 2004, because that method 2 election related to an earlier cost reporting period and not to the cost reporting period beginning January 1, 2004. The same result would occur if the CAH had elected method 2 on October 1, 2003, but subsequently revoked that election on October 15, 2004.

In the proposed rule, we proposed to revise §413.70(b)(3)(i) to reflect the changes made by section 405(d) of Pub. L. 108-173. We proposed to specify in §413.70(b)(3)(i) that a CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004, under the method described in §§413.70(b)(3)(ii) and (b)(3)(iii). In §413.70(b)(3)(i)(A), we proposed to clarify that such an election is to be made at least 30 days before the start of the cost reporting period for which the election is made. In §413.70(b)(3)(i)(B), we proposed to specify that the provision applies to all services furnished to outpatients during that cost reporting period by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with the reassignment regulations under 42 CFR Part 424, Subpart F. In that paragraph, we also proposed to specify that if a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with 42 CFR Part 424, Subpart F, payment for the physician's or practitioner's services to CAH outpatients will be made on a fee schedule or other applicable basis specified in 42 CFR Part 414, Subpart B. We also proposed to add a new paragraph (C) to §413.70(b)(3)(i) to state that, in case of a CAH that made an election under §413.70(b)(3) before November 1, 2003, for a cost reporting period beginning before December 1, 2004, the rules in paragraph (b)(3)(i)(B)

are effective for cost reporting periods beginning on or after July 1, 2001. In addition, we proposed in §413.70(b)(3)(i)(B) to clarify that an election for the optional method would be effective only for any cost reporting period for which it was made and does not apply to an election that was withdrawn or revoked before the start of the cost reporting period for which it was made.

We did not receive any public comments on our proposals. Accordingly, in this final rule, we are adopting the proposals as final without modification.

4. Coverage of Costs for Certain Emergency Room On-Call Providers (Section 405(b) of Pub. L. 108-173 and §§413.70(b)(4) and 485.618 of the Regulations)

Under existing regulations at §413.70(b)(4), which implement section 1834(g)(5) of the Act, Medicare payments to a CAH may include the costs of compensation and related costs of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the reasonable cost of outpatient CAH services.

Section 405(b) of Pub. L. 108-173 amended section 1834(g)(5) of the Act to expand the reimbursement to a CAH of compensation costs for on-call emergency room providers beyond physicians to include physician assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services furnished on or after January 1, 2005.

In the May 18, 2004 proposed rule (69 FR 28329), we proposed to revise §413.70(b)(4)(i) and (ii) to include the expanded list of emergency room on-call providers for whom reimbursement for reasonable compensation and related costs in a

CAH would be available. We also proposed to make a conforming change to §485.618(d) governing the standard for emergency room personnel who are on call under the CAH conditions of participation.

Comment: One commenter recommended that the proposed change to §485.618(d), under which a clinical nurse specialist is added to the list of practitioners who may be on call to provide emergency services to CAH patients, be revised by adding a comma after the phrase "clinical nurse specialist." The commenter believed this change will help to clarify that all practitioners who have on-call responsibilities, and not only clinical nurse specialties, should have training or experience in emergency care.

Response: We agree and have made this change to §485.618(d) and a conforming change to §413.70(b)(4)(ii)(B) in this final rule.

Accordingly, in this final rule, we are adopting the proposed changes to §485.618(d) as final with one further technical change, as discussed above, to clarify that all practitioners who have on-call responsibilities should have training or experience in emergency care.

5. Authorization of Periodic Interim Payments for CAHs (Section 405(c) of Pub. L. 108-173 and Proposed §§413.64(h)(2)(vi) and 413.70(d) of the Regulations)

Section 1815(e)(2) of the Act provides that payments may be made on a periodic interim payment (PIP) basis for specified covered Medicare services. Section 405(c)(1) of Pub. L. 108-173 amended section 1815(e)(2) of the Act by adding a new subsection (E) to provide for payments for inpatient services furnished by CAHs on a PIP basis, effective for payments made on or after July l, 2004. Section 405(c)(2) of

Pub. L. 108-173 directs the Secretary to develop alternative methods for the timing of the payments under the PIP method.

We have already established in existing regulations under §413.64(h) provisions for making payments under the PIP method to providers for certain Medicare covered services. The principles and rules of §413.64 have been incorporated into regulations governing payment on a PIP basis to acute care IPPS hospitals as well as to other providers, such as SNFs and LTCHs, that are paid on a prospective basis. We believe these principles and rules could be equally applied to CAHs. Therefore, in the May 18, 2004 proposed rule (69 FR 28329), to implement the provisions of section 405(c) of Pub. L. 108-173, we proposed to add a new §413.64(h)(2)(vi) to specify inpatient services furnished by CAHs as an additional type of covered service for which PIP is available, effective for payments made on or after July 1, 2004.

It has been our longstanding policy under §413.64(h)(6) that payment will be made biweekly under the PIP method, unless the provider requests a longer fixed interval (not to exceed 1 month) between payments. We believe that this provision grants adequate flexibility for the timing of payments under the PIP method to all qualifying providers, including CAHs. Under the proposed policy for CAHs, if a CAH chooses to receive its payments less frequently than biweekly, it could inform its Medicare fiscal intermediary. Section 413.64(h)(6) does not provide for the payments to be made more frequently than biweekly to providers for which PIP is currently available. We believe this is equally appropriate for the payments for inpatient services furnished by CAHs.

In summary, we proposed to apply the same rules and procedures for payments under the PIP method that we apply to acute care hospitals and certain other Medicare providers. Therefore, CAHs, in applying for and receiving payments for inpatient services under the PIP provision, would be operating under the same rules as other providers for which PIP is available under §413.64(h), including the flexibility discussed above of the timing of their payments as provided for under §413.64(h)(6). We also proposed to establish a new paragraph (d) under §413.70 to provide that, for payments on or after July l, 2004, a CAH may elect to receive PIP for inpatient services furnished by CAHs, subject to the provisions of §413.64(h). The new §413.70(d) summarizes the application of the PIP provisions under §413.64(h)(6) for CAH inpatient services and notes the availability of accelerated payments for CAHs that are not receiving PIPs.

Comment: Two commenters noted that section 405(c) of Pub. L. 108-173 provides that PIP for CAHs applies to payments made on or after July 1, 2004. One commenter believed that the new paragraph (d) under §413.70 providing for PIP for CAHs "subject to the provisions of §413.64(h)" suggests that payment of PIP would be for cost reports beginning on or after July 1, 2004. The commenters stated that some fiscal intermediaries have indicated that existing CAH facilities will not be able to receive PIP until the start of their first cost reporting period beginning on or after July 1, 2004 and that a CMS regional office has provided direction that the election of PIP is limited to the beginning of a CAH cost reporting period. The commenters asked CMS to clarify that qualifying CAHs are eligible for PIP, effective for payments made on or after July 1, 2004, not for cost reports beginning on or after that date.

Response: Qualifying CAHs are eligible for PIP for payments made on or after July 1, 2004. New §413.64(h)(2)(vi) specifies that for inpatient CAH services furnished by a CAH, PIP is available for qualifying CAHs, effective for payments made on or after July 1, 2004. New §413.70(d) also provides that a CAH may elect to receive PIP effective for payments made on or after July 1, 2004. Section 413.64(h)(3) has long provided that a provider that establishes to the satisfaction of its fiscal intermediary that it meets the requirements to receive PIP may elect to receive PIP, beginning with the first month after its request that the fiscal intermediary finds administratively feasible. This provision provides fiscal intermediaries some flexibility in beginning PIP for a provider, but we expects that fiscal intermediaries will begin PIP for providers, including CAHs, within a reasonable period of time after the fiscal intermediary has determined that the provider qualifies for PIP.

Comment: One commenter indicated that some fiscal intermediaries have interpreted the regulations at §413.64(h) that a new CAH cannot receive PIP until at least one CAH cost report has been filed. Another commenter indicated that one CMS regional office has suggested that PIP is only available to those CAHs that have at least one full 12-month cost report under cost-based reimbursement.

Response: Section 413.64(h)(3)(ii) has long contained the requirement that, to qualify for PIP, the provider has filed at least one completed Medicare cost report accepted by the fiscal intermediary as providing an accurate basis for computation of payment. However, the requirement contains an exception in the case of a provider requesting payment under PIP upon first entering the Medicare program. Therefore, a

new CAH to the Medicare program need not have filed a cost report to be able to qualify for PIP. However, in the absence of a completed cost report, the fiscal intermediary must have other information in order to satisfy itself that it can make accurate PIP payments. A provider without a completed cost report needs to supply all information that the fiscal intermediary requests in order for the intermediary to make its determination as to whether it can make accurate payments to the provider under the PIP method. Section 413.64(h)(5) provides that approval of PIP is conditioned upon the intermediary's best judgment as to whether accurate payments can be made under the PIP method. Therefore, if the fiscal intermediary is satisfied with the information it has received that it can make accurate payments under the PIP method, it will approve PIP for the provider. If the fiscal intermediary is not satisfied that it can make accurate payments, it is not to approve PIP for the provider.

A CAH need not have at least one full 12-month cost report under cost-based reimbursement to qualify for PIP. However, as discussed above, a fiscal intermediary is not to approve PIP unless it is satisfied that PIP will result in accurate payments. For a provider without a full 12-month cost report under cost reimbursement, the fiscal intermediary may request additional information from the provider in order to assure itself that it can make accurate payment to the provider under PIP. If the fiscal intermediary is satisfied with the information it has received that it can make accurate payments under the PIP method, it will approve PIP for the provider. If the fiscal intermediary is not satisfied, it is not to approve PIP for the provider.

After careful consideration of the comments received, we do not believe any changes are necessary, and we are adopting our proposal as final without modification.

Technical Changes to §413.64. In the May 18, 2004 proposed rule, we proposed to use this opportunity to remove §§413.64(h)(3)(iv) and 413.64(h)(4), which contain an outdated requirement that a provider must repay any outstanding current financing payments before being permitted to be paid under the PIP method. Current financing payments have not been available since 1973. We did not receive any public comments on this proposed technical change. Therefore, we are adopting it as final.

6. Revision of the Bed Limit for CAHs (Section 405(e) of Pub. L. 108-173 and §§485.620(a) and 485.645(a)(2) of the Regulations)

Prior to the enactment of Pub. L. 108-173, sections 1820(c)(2)(B)(iii) and 1820(f) of the Act restricted CAHs to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. The number of beds used at any time for acute care inpatient services could not exceed 15 beds.

Section 405(e) of Pub. L. 108-173 amended sections 1820(c)(2)(B)(iii) and 1820(f) of the Act to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. This amendment is effective on January 1, 2004 and applies to CAHs designated before, on, or after this date. However, section 405(e)(3) of Pub. L. 108-173 also notes that any election made in accordance with the regulations promulgated to carry out the bed size amendments only applies prospectively.

We implemented this provision via a survey and certification letter on January 1, 2004. (See Survey and Certification Letter No. 0414, issued December 11, 2003.) Effective January 1, 2004, this provision allows any currently participating CAH, or applicant for CAH approval, to maintain up to 25 inpatient beds. If swing-bed approval has been granted, all 25 beds can be used interchangeably for acute care or swing-bed services. However, no CAH will be considered to have had 25 acute care beds prior to January 1, 2004. In the May 18, 2004 proposed rule (69 FR 28329), we proposed to amend our regulations at §§485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds permitted in a CAH, in accordance with the amendments made by section 405(e) of Pub. L. 108-173.

We received no comments within the scope of this proposal and, in this final rule, we are adopting as final, without modification, our proposed amendments to §§485.620(a) and 485.645(a)(2) to reflect the increase in the number of beds to 25 permitted in a CAH, in accordance with the amendments made by section 405(e) of Pub. L. 108-173.

7. Authority to Establish Psychiatric and Rehabilitation Distinct Part Units of CAHs (Section 405(g)(1) of Pub. L. 108-173 and New §485.646 of the Regulations)

As stated earlier, sections 1820(c)(2)(B) and 1861(mm) of the Act set forth the criteria for designating a CAH. Under this authority, the Secretary has established in regulations the minimum requirements a CAH must meet to participate in Medicare (42 CFR Part 485, Subpart F). The CAH designation is targeted to small rural hospitals with a low patient census and short patient stays.

Under the law in effect prior to Pub. L. 108-173, CAHs are excluded from operating distinct part units (that is, separate sections of hospitals that are dedicated to providing inpatient rehabilitation or psychiatric care and are paid under payment methods different from those used for the acute care areas of the hospitals). The statute (section 1886(d)(l)(B) of the Act) and implementing regulations under 42 CFR Part 412, Subpart B require distinct part units to be units of "subsection (d) hospitals," which are hospitals paid under the IPPS. Because CAHs are not "subsection (d) hospitals" paid under IPPS, but instead are paid for inpatient care on a reasonable cost basis under section 1814(l) of the Act, they are effectively prohibited from having distinct part units.

Section 405(g)(1) of Pub. L. 108-173 modified the statutory requirements for CAHs under section 1814(l) and section 1820(c)(2) of the Act to allow CAHs to establish distinct part rehabilitation and psychiatric units of up to 10 beds each, which will not be included in the revised total 25 CAH bed count under section 405(e) of Pub. L. 108-173 (discussed in detail in section VI.D.6. of this preamble). In addition, as explained more fully below, the average 96-hour stay does not apply to the 10 beds in the distinct part units and inpatient admissions; days of inpatient care in these distinct part units are not taken into account in determining the facility's compliance with the requirement for a facility-wide average length of stay that does not exceed 96 hours.

Section 405(g)(1) of Pub. L. 108-173 provides under section 1820(c)(2)(E)(i) of the Act that a distinct part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to the distinct part unit of a hospital if the distinct part unit were established by a subsection (d) hospital in

accordance with the matter following clause (v) of section 1886(d)(1)(B) of the Act, including any applicable regulations adopted by the Secretary. CAHs will now be permitted to operate distinct-part psychiatric and rehabilitation units, and it is clear that the law, consistent with this change, requires the same level of health and safety protection for patients in distinct part units of a CAH that is currently required for patients in distinct part units operated by an acute care hospital. The amendments to section 405(g)(1) Pub. L. 108-173 are effective for the cost reporting periods beginning on or after October 1, 2004.

As CAHs were excluded from operating distinct part units prior to the enactment of section 405(g) Pub. L. 108-173, the CAH conditions of participation did not address the necessary requirements and standards for operating such units. As noted previously, section 1820(c)(2)(E)(i) of the Act makes it clear that the requirements, including conditions of participation, for operating these units in a CAH are to be the same as is currently required for these units operated by an acute care hospital. Accordingly, we proposed that, in accordance with the requirements of section 405(g) Pub. L. 108-173, a rehabilitation or psychiatric distinct part unit of a CAH must meet all of the hospital conditions of participation at 42 CFR Part 482, Subparts A, B, C, and D and the criteria for exclusion from the IPPS at 42 CFR Part 412 as described below. These requirements will only apply to the services provided in the distinct part unit of a CAH and not the entire CAH.

Currently, psychiatric distinct part units of hospitals are subject to specific Medicare regulations established in 42 CFR 412.27 regarding the types of patients admitted, the scope of services furnished, and the qualifications of staff. For example, psychiatric distinct part

units may admit only patients whose condition requires inpatient hospital care for a psychiatric principal diagnosis. The regulations at §412.27(b) further requires a hospital that wishes to establish a psychiatric distinct part unit to furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and occupational and recreational therapy. The hospital must maintain medical records for the unit that permit determination of the degree and intensity of services provided to individuals treated in the unit. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program, and who is board certified in psychiatry (42 CFR 412.27(d)(2)). The distinct part unit must have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. There must also be an adequate number of registered nurses to provide 24-hour coverage as well as licensed practical nurses and mental health workers. These and other applicable requirements are set forth in greater detail in §412.27.

Rehabilitation distinct part units of hospitals are currently subject to criteria in 42 CFR 412.29. This section specifies that such a unit must meet either the requirements for new units (§412.30(a)) or those for existing units (§412.30(c)). In addition, the units must furnish through qualified personnel rehabilitation nursing, physical and occupational therapy, and, as needed, speech therapy and social services or psychological services, and orthotics and prosthetics. The unit must have a director of rehabilitation services who is trained or

experienced in medical management of inpatients who require rehabilitation services and is a doctor of medicine or a doctor of osteopathy. Rehabilitation distinct part units may treat only patients likely to benefit significantly from an intensive inpatient program, utilizing services such as physical, occupational, or speech therapy. These and other applicable requirements are set forth in greater detail in §412.29 and §412.30.

To implement the requirements of section 1820(c)(2)(E)(i) of the Act, as added by section 405(g)(1) of Pub. L. 108-173, in the May 18, 2004 proposed rule (69 FR 28330), we proposed to add a new §485.647 to 42 CFR Part 485, Subpart F. In proposed §485.647(a)(1), we proposed to specify that if a CAH provides inpatient psychiatric services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in §412.25(a)(2) through (f), and with the additional requirements of §412.27 for psychiatric units excluded from the IPPS. In proposed §485.647(a)(2), we proposed to specify that if a CAH provides inpatient rehabilitation services in a distinct part unit, the services provided in that unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482, with the common requirements for IPPS-excluded units in §412.25(a)(2) through (f), and with the additional requirements of §412.29 and §412.30, which relate specifically to rehabilitation units excluded from the IPPS. To provide for consistent application of section 405(g)(1) Pub. L. 108-173 and avoid any confusion, we also proposed to revise §412.22, which contains the common requirements for excluded hospital units, to state that, for purposes of 42 CFR Part 412, Subpart B, the term “hospital” includes a CAH.

As noted earlier, sections 1820(c)(2)(E)(ii) and (c)(2)(E)(iii) of the Act, as added by section 405(g)(1) of Pub. L. 108-173, provide that each distinct part unit of a CAH may have up to 10 beds and that, in determining the number of beds a CAH has for purposes of compliance with the 25-bed limit described earlier, the beds in a distinct part unit are not to be taken into account. We interpret the exclusion of these beds from consideration for purposes of the 25-bed limit as also indicating that the admissions and lengths of stay in distinct part unit beds are not to be considered in determining the facility-wide average length stay of a CAH for purposes of the 96-hour limitation on CAH's average length of inpatient stay. We proposed to codify these rules in paragraphs (b)(1) through (b)(3) of proposed §485.647.

Section 1820(c)(2)(E)(iv) of the Act, as added by section 405(g)(1) of Pub. L. 108-173, imposes severe sanctions on CAHs that fail to operate their distinct part units in compliance with applicable requirements. That section states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(e)(2)(E)(i) of the Act with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the CAH unit has demonstrated to CMS that the unit meets the requirement of section 1820(e)(2)(E)(1) of the Act. We proposed to codify this requirement by adding a new paragraph (g) to §412.25, which contains the common requirements for excluded units.

Section 405(g)(1) of Pub. L. 108-173 amended section 1814(l) of the Act by adding a new paragraph (2) to that provision. New section 1814(l)(2) of the Act states that, in the case of a distinct-part psychiatric or rehabilitation unit of a CAH, the amount of payment for inpatient CAH services of such a unit is to equal the amount that would be paid if these

services were inpatient hospital services of a psychiatric or rehabilitation unit, respectively, of the kind described in the matter following clause (v) of section 1886(d)(1)(B) of the Act. To implement the requirements of section 1814(1)(2) of the Act, we proposed that, for CAHs that establish rehabilitation or psychiatric distinct part units, or both, in their facility, Medicare payment for inpatient services provided in those units would be made under the applicable existing payment methodology described below for IRFs and IPFs.

Presently, IRFs are paid under a per discharge PPS that became effective for cost reporting periods beginning on or after January 1, 2002. The regulations governing the IRF PPS are located under 42 CFR Part 412, Subpart P (§412.600 through §412.632).

At this time psychiatric hospitals and units that are excluded from the IPPS are paid for their inpatient operating costs on a reasonable cost basis, subject to a hospital-specific limit. However, as required by statute, a per diem PPS for Medicare payments for inpatient hospital services furnished in psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)) was proposed in the **Federal Register** on November 28, 2003 (68 FR 66920). We are in the process of developing the final rule for this proposed rule. When finalized, the IPF PPS will replace the reasonable cost based payment system currently in effect.

To clarify the requirements of section 1814(1)(2) of the Act regarding payment for inpatient CAH services of a distinct part psychiatric or rehabilitation unit of a CAH, in the May 18, 2004 proposed rule, we proposed to revise the title and first sentence of paragraph (a)(1) of §413.70, and to add a new paragraph (a)(4) to that section, to clarify that payment for inpatient services of a CAH distinct part unit is not made in accordance with the otherwise

applicable rules for payment for inpatient CAH services, but under other rules described in new §413.70(e). We also proposed in new paragraph §413.70(e), that payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the IRF PPS at 42 CFR Part 412, Subpart F (§412.600 through §412.632). We also proposed to state that payment for inpatient services of distinct part psychiatric units of CAHs is made in accordance with regulations governing IPPS-excluded psychiatric units of hospitals at 42 CFR 413.40.

Comment: One commenter expressed concern with the requirement that a CAH must have an "adequate" number of doctors with appropriate qualifications "to provide essential psychiatric services." The commenter was concerned that, due to the small size of CAHs and the limited number of psychiatrists in rural areas, CAHs may hire psychiatrists who spend only a small portion of their time at the CAH. The commenter suggested that we consider requiring clinical directors to devote a specified minimum amount of time to each psychiatric unit they serve to offset the possibility of an inadequate supply of physicians.

Response: We believe the clinical director must devote the appropriate amount of time to meet the needs of the patients in the unit. We stated in the proposed rule that CAHs that operate a distinct-part psychiatric unit must comply with the same health and safety requirements as other Medicare-certified acute care hospitals that operate distinct-part psychiatric units. Currently, distinct-part psychiatric units of hospitals are subject to specific Medicare regulations regarding the staff and scope of services for psychiatric inpatient care. In addition to a clinical director, the distinct-part psychiatric unit must

have a director of social services, a qualified director of psychiatric nursing services who is a registered nurse with a master's degree in psychiatric or mental health nursing, or its equivalent from an accredited school of nursing, or is qualified by education and experience in the care of individuals with mental illness. We believe that these requirements, and others set forth in greater detail in §412.27, are required to l safeguard the care of individuals in a CAH distinct-part psychiatric unit.

Comment: One commenter stated that requiring CAH distinct part psychiatric and rehabilitation units to meet all of the hospital conditions of participation at 42 CFR Part 42, Subparts A, B, C and D will require both the JCAHO and the State survey agencies to conduct two surveys when assessing CAHs. The commenter stated that this requirement would result in a burdensome oversight strategy that would cause CAHs to decide not to add distinct part units.

Response: Section 405(g)(1) of Pub. L. 108-173 states that a distinct-part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to a distinct-part unit of a hospital. Therefore, we believe that it is clear that the Congress wants the same level of health and safety protection for patients in a distinct-part unit operated by a CAH as those that are currently required for patients in a distinct-part unit operated by an acute care hospital.

Therefore, it will be necessary for a distinct-part psychiatric or rehabilitation unit of a CAH to undergo a survey to demonstrate compliance with the requirements stipulated in the statute. Until a CAH receives approval and a provider number from CMS for any DPUs, the services furnished in those units will not be eligible for Medicare

reimbursement. The CAH is not required to furnish such uncompensated services to Medicare beneficiaries prior to its approval.

Comment: As previously noted, proposed §412.25(g) would require denial of payment to a CAH for services of a distinct-part psychiatric or rehabilitation unit of a CAH if that unit does not meet the requirements of proposed §485.647 with respect to a cost reporting period. Under the proposal, no payment may be made to the CAH for services furnished in that unit for that period. The section further states that payment to the CAH for services in the unit may resume only after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.

One commenter stated that the rule is unclear as to whether, if a failure to meet proposed §485.647 is both noted and corrected in the same cost reporting period, would payment resume as soon as the noncompliance is corrected. The commenter recommended that the section be revised to state that payment will be denied only from the date on which the deficiency was noted to the date on which it was corrected.

Response: We do not believe that the commenter's recommendation is supported by the statute. As noted above, section 405(g)(1) of Pub. L. 108-173, states that if a psychiatric or rehabilitation unit of a CAH does not meet the requirements of section 1820(c)(2)(E)(i) of the Act with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Because the law is so specific on this issue, we do not have the flexibility to resume payment for services of a unit during any part of the same period in which the unit fails to meet applicable requirements of section 1820(c)(2)(E)(i) of the Act, as implemented by the regulations in

new §485.649. On the contrary, the law would permit payment to the CAH for services for such a unit to resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647. We have revised §412.25(g) to clarify that. Payment to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.

Although we considered carefully the comments received regarding distinct-part units of CAHs, we concluded that they did not raise considerations that would require changes to the proposed rule. Therefore, in this final rule, we are adopting as final the proposed amendments to §413.70(a)(1) and the proposed addition of §413.70(a)(4), §413.70(e), and §485.647 to implement the requirements under section 405(g)(1) of Pub. L. 108-173 for CAHs to establish and receive payment under Medicare for psychiatric and rehabilitation distinct part units. In the May 18 2004, proposed rule, we proposed to implement this provision under proposed §485.647. However, the statute would permit payment to the CAH for services of such a unit to resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of proposed §485.647. In this final rule, we are revising §412.25(g) to clarify that payments to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.

Comment: Several commenters questioned how distinct-part unit beds are to be classified in a CAH if the facility had distinct-part unit beds prior to converting to a

CAH. The commenters inquired if the distinct-part unit beds will be considered new or converted beds.

Response: In order for Medicare to classify a provider as a CAH, the provider must meet specific regulatory requirements. Therefore, we believe a CAH evolved into a different provider classification from the type of provider it was prior to converting to a CAH. Under the statute in effect prior to Pub. L. 108-173, a CAH was not allowed to establish an inpatient rehabilitation DPU. Section 405(g)(1) of Pub. L. 108-173 modified the statutory requirements for CAHs under section 1820(c)(2) of the Act to allow a CAH to establish a rehabilitation DPU of up to 10 beds. A CAH that meets all inpatient rehabilitation DPU regulatory requirements, on or after the effective date of this final rule, will be allowed to establish an inpatient rehabilitation DPU whose size does not exceed 10 beds. According to §412.30(b)(1)(i), a new unit is a hospital unit that the hospital has not previously sought to exclude from the IPPS. In addition, before the hospital unit may be considered a new unit, §412.30(b)(1)(ii) of our regulations requires that the hospital have "obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit." Because a CAH is a different provider from the entity it was prior to converting to being a CAH, and was not previously allowed to establish an inpatient rehabilitation DPU, a CAH never sought exclusion for any inpatient rehabilitation unit. Therefore, if a CAH establishes an inpatient rehabilitation DPU, that DPU will be considered to be a new unit in accordance with §412.30(b)(1)(i) of our

regulations, as long as the CAH also meets the requirements specified in §412.30(b)(1)(ii) of our regulations.

Comment: One commenter requested that their hospital be grandfathered into the CAH program and be allowed to maintain a 15-bed psychiatric distinct-part unit.

Response: We do not have the authority to grandfather a hospital into the CAH program. A facility can be certified as a CAH if the facility is designated as a CAH by the State survey agency or by CMS and found to meet the conditions of participation in 42 CFR 485, Subpart F. Regardless, the statute does not allow CAHs to exceed the 10-bed limit for distinct-part units.

We considered carefully the comments received regarding distinct-part units of CAHs. To implement the requirements under section 405(g)(1) of Pub. L. 108-173 for CAHs to establish and receive payment under Medicare for psychiatric and rehabilitation distinct part units, in this final rule, we are adopting the proposed amendments to §413.70(a)(1) and the proposed addition of §§413.70(a)(4), 413.70(e), and 485.647 as final, with one modification. That is, we are revising §412.25(g) to clarify that payments to the CAH for services provided in such a unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.

8. Waiver Authority for Designation of a CAH as a Necessary Provider

Section 405(h) of Pub. L. 108-173 amended section 1820(c)(B)(i)(II) of the Act by adding language that terminates a State's authority to waive the location requirement for a CAH by designating the CAH as a necessary provider, effective January 1, 2006.

Currently, a CAH is required to be located more than a 35-mile drive (or in the case of mountainous terrain or secondary roads, a 15-mile drive) from a hospital or another CAH, unless the CAH is certified by the State as a necessary provider of health care services to residents in the area. Under this provision, after January 1, 2006, States will no longer be able to designate a CAH based upon a determination that it is a necessary provider of health care.

In addition, section 405(h) of Pub. L. 108-173 amended section 1820(h) of the Act to include a grandfathering provision for CAHs that are certified as necessary providers prior to January 1, 2006. Under this provision, any CAH that is designated as a necessary provider in its State's rural health plan prior to January 1, 2006, will be permitted to maintain its necessary provider designation.

In the May 18, 2004 proposed rule (69 FR 28331), we proposed to revise our regulations at §485.610(c) to incorporate the amendments made by section 405(h) of Pub. L. 108-173.

Comment: Commenters were concerned that some hospitals may receive the necessary provider designation by the State before January 1, 2006, but would not have had enough time to complete the State survey and certification process in order to be fully converted to a CAH by January 1, 2006. The commenters recommended that we grandfather a hospital that is certified as a necessary provider by January 1, 2006, as long as that hospital is continuing the process toward conversion to a CAH.

Response: Both the preamble and the regulations text concerning this issue in the proposed rule state that a CAH that is designated as a necessary provider in its State's

rural health plan as of January 1, 2006, will maintain its necessary provider designation after January 1, 2006. However, in keeping with the clear intent of section 405(h) of Pub. L. 108-173, if a facility is not a CAH as of January 1, 2006, the ability to be designated as a necessary provider before becoming a CAH will no longer exist after January 1, 2006. Extending the time to allow for such a facility to convert to a CAH would violate this intent. Therefore, we are not accepting these commenters' recommendation.

Comment: One commenter stated several CAHs in Nebraska are considering replacing their aged facilities and wanted to know if a CAH could retain its necessary provider status if it relocates. The commenter inquired if the necessary provider status would remain with the provider number and not be determined by the physical location of the building.

Response: There are many factors involved with a relocation of a CAH that may or may not change a CAH's status as a necessary provider. It is not possible to make a statement in this final rule that would apply to all situations. The issue of retaining a necessary provider status after a CAH relocates is a local certification issue that the regional offices will evaluate on a case-by-case basis.

In this final rule, we are adopting as final, without modification, the provisions of §485.610(c) that incorporates the amendments made by section 405(h) of Pub. L. 108-173.

9. Payment for Clinical Diagnostic Laboratory Tests

Medicare payment for clinical diagnostic laboratory tests provided to the outpatients of CAHs was established through the regulatory process and published in the **Federal Register** as part of the FY 2004 IPPS final rule (68 FR 45346, August 1, 2003). Payment to a CAH for clinical diagnostic laboratory tests for outpatients is made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH and are physically present at the CAH at the time specimens are collected. Otherwise, payment for these tests is made on a fee schedule basis.

We published this final rule to clarify our policy in this area and ensure that all relevant issues were publicly noted. For reasons which are set forth in detail in the FY 2004 IPPS final rule, we do not agree that providing reasonable cost payment to individuals who are not present at the CAH when the specimen is collected is appropriate. We believe that extending reasonable cost payment in these instances is inconsistent with Medicare law and regulations and duplicates existing coverage. It also creates confusion for beneficiaries and others by blurring the distinction between CAHs and other types of providers (for example, SNFs and HHAs) and increases the costs of providing care to Medicare patients without enhancing either the quality or the availability of that care.

Following publication of the FY 2004 IPPS final rule, we received a number of letters and statements in Open Door Calls indicating that some commenters continue to believe that this policy will impose a hardship on Medicare beneficiaries in rural areas. Several of these commenters argued that it might cause frail elderly nursing home patients to have to be moved to a CAH to have blood drawn or other specimen collection

performed instead of sending a laboratory technician to the patient's bedside for the same purpose. We agree with the commenters that this would not be an appropriate result. However, we would note that there are also alternative ways in which specimen collection and travel are payable under Medicare (for example, the laboratory benefit under Part B or HHAs that have laboratory provider numbers). Therefore, we do not expect beneficiaries to face reduced access to services under this policy.

In response to continuing claims of potential access problems, we invited commenters to submit further, more specific comments that provide specific information on actual, rather than merely potential or anticipated access problems. In response, we received many communications asserting that these problems would occur, but no credible documentation that they actually are occurring. As a result of these responses, we did not propose any further change in policy on this issue in the May 18, 2004 proposed rule (69 FR 28331-28332). We indicated that we would like to renew our request for specific, verifiable documentation as to any actual access problems being generated by this policy, and would review carefully any such documentation we receive to determine whether current policy should be reconsidered.

Comment: Some commenters asserted that CMS policy in this area is shortsighted and not in the best interest of rural beneficiaries or hospitals, or that it would restrict access to laboratory services in rural areas, but provided no documentation of access problems or other evidence to support their assertions.

Response: While we read the commenters' letters with interest, we noted that they merely restated former comments, but did not provide any objective evidence in

support of their comments that maintaining the current policy regarding payment for clinical diagnostic laboratory tests would compromise access to these tests in rural areas. Therefore, we made no changes in our policy in this area based on these comments.

Comment: One commenter stated that five CAHs in the commenter's State (Kansas) have either eliminated or seriously limited the processing of specimens drawn from off-site locations in response to the payment policy for clinical diagnostic laboratory tests.

Response: We appreciate this additional information and will take it into account as we consider whether any revision should be made to this policy.

10. Continued Participation by CAHs in Counties Reclassified as Urban Based on the 2000 Census

Under section 1820(c)(2)(B)(i) of the Act, a facility is eligible for designation as a CAH only if it is located in a county or equivalent unit of local government in a rural area (as defined in section 1886(d)(2)(D) of the Act), or is being treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. The regulations implementing this location requirement are located at 42 CFR 485.610(b)(2). As previously noted, some facilities currently participating as CAHs are located in counties which are located in areas considered as "rural areas" in FY 2004 under the definition in section 1886(d)(2)(D) of the Act but will, as of October 1, 2004, be considered to be located in MSAs because of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003. We received a number of comments on this issue.

Comment: Several commenters recommended that CMS exercise executive discretion to allow continued CAH participation by facilities which are currently (that is, for FY 2004) participating as CAHs but are located in counties which will be considered part of MSAs effective October 1, 2004, as a result of data from the 2000 census and implementation of the new MSA definitions announced by OMB on June 6, 2003. The commenters stated that if such facilities' CAH participation were terminated, they would be likely to again seek State licensure and Medicare participation as hospitals in order to be able to continue operations. However, this change to hospital status would not be automatic but would require the facility either to be re-licensed as a hospital by the State and to successfully demonstrate compliance with the hospital conditions of participation (COPs) based either on a CMS survey conducted by the State survey agency under contract with CMS, or on hospital accreditation by the JCAHO or the American Osteopathic Association (AOA). Once the facility has resumed participation as defined under section 1886(d) of the Act, the facility could then be treated as a "rural" hospital under section 1886(d)(8)(E)(ii)(II) of the Act, which provides such treatment for any hospital located in an area designated by law or regulation of the State as a rural area. If the facility were to obtain such a designation and met other criteria for CAH conversion, it would then be qualified for designation by the State and certification by CMS as a CAH, notwithstanding its location in an MSA. The commenters believed such a sequence of changes in the status of a facility (that is, from being a CAH to being a hospital to again being a CAH) would be costly and time consuming for both the facility and CMS, and would not serve any useful purpose, because at the conclusion of the

process the facility would resume participating as a CAH, as it did during FY 2004. Therefore, some of these commenters recommended that CMS continue to treat CAHs in such counties as being rural for an indefinite time period. Other commenters recommended that CAHs in such counties be considered rural until at least January 1, 2006, in order to allow them an opportunity to obtain rural designations under applicable State law or regulations from their State legislatures or regulatory agencies.

Another commenter did not recommend any particular course of action to be taken by CMS, but asked whether there were any plans to develop a grandfather provision to avoid a break in CAH participation by facilities affected by the new census results.

Response: We agree with the commenters' concerns and are revising §485.610 by adding a new paragraph (b)(3) to provide special treatment for such facilities. Under the new paragraph, a CAH that is located in a county that, in FY 2004, was not part of a MSA as defined by the OMB, but as of FY 2005 was included as part of a MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, would nevertheless be considered to meet the rural location requirement and, therefore, could continue participating without interruption as a CAH from October 1, 2004, through the earlier of the date on which the CAH obtains a rural designation under §412.103, or December 31, 2005. Such a facility would be allowed to continue participating as a CAH and would not be required to convert back to being a hospital unless it was not able to obtain a rural designation under §412.103. We

are also amending §412.103 to clarify that such a CAH is eligible for rural designation under that section.

Comment: One commenter suggested that changes in the status of an area from rural to urban as a result of the most recent census data and implementation of the new MSA definitions be applied only for purposes of determining the wage index values for providers paid under a system that uses a wage index adjustment, and not for determining a rural location for purposes of eligibility of a facility to participate in Medicare as a CAH.

Response: We reviewed this suggestion but concluded that section 1820 of the Act, which specifically refers to rural areas as, defined in sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act, do not authorize us to implement the new census results and MSA designation rules in such a selective way. Therefore, in this final rule, we are not adopting this recommendation.

11. Proposed Technical Changes in Part 489

In several sections of Part 489, we have discovered a need to update cross-references to conform them to the redesignation of the Medicare transfer rules from §489.24(d) to §489.24(d). Specifically, as we proposed in the May 18, 2004 proposed rule (69 FR 28332), we are correcting the cross-reference to "§489.24(d)" in §§489.20(m) and 489.53(b)(2) to read "§489.24(e)".

12. Issues Beyond the Scope of the Proposed Rule.

In the proposed rule published on May 18, 2004, we proposed changes affecting CAHs only if they were related to MSA definitions and the results of the 2000 census, or to the provisions of section 405 of Pub. L. 108-173. In addition, as previously noted, we requested documentation regarding the effects of the rule on payment for clinical diagnostic laboratory tests by a CAH, but did not propose any change in that rule.

In response to the proposed rule, many commenters chose to raise issues that are beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments in this document. However, we will review the comments and consider whether to take other actions, such as revising or clarifying CMS program operating instructions or procedures, based on the information and recommendations in the comments.

VII. Changes to the Disclosure of Information Requirements for Quality Improvement Organizations (QIOs)

A. Background

Section 1152 of the Act defines a utilization and quality control peer review organization (now referred to as a quality improvement organization (QIO). Section 1153 provides for contracts with such organizations to review items and services furnished by physicians, other practitioners, and providers to Medicare patients to verify that the items and services are reasonable, medically necessary, and allowable under the Act; meet professionally recognized standards of health care; and are furnished in the appropriate setting. Section 1154 of the Act outlines the functions of a QIO, which include responsibility for: (1) collecting and maintaining information necessary to carry out its responsibilities; (2) examining pertinent records maintained by the practitioner or provider verifying the medical necessity and quality of services provided by any practitioner or provider of health care services to Medicare patients; (3) ensuring that health care practitioners and providers maintain evidence of medical necessity and quality of health care services provided to Medicare patients; and (4) exchanging information with intermediaries, carriers, and other public or private review organizations as appropriate. Section 1160 of the Act provides that information acquired by QIOs in the exercise of their duties and functions must be held in confidence. Information cannot be disclosed except as allowed under section 1160 of the Act and the existing regulations governing the release of QIO peer review information in 42 CFR Part 480. Specifically, Part 480 sets forth the policies and procedures for disclosure of information collected, acquired, or generated by a QIO (or the review component of a QIO subcontractor) in the performance of its responsibilities under the Act and the Medicare regulations, as well as

the acquisition and maintenance of information needed by a QIO to comply with its responsibilities under the Act.

QIOs assist institutions and practitioners seeking to improve the quality of care given to Medicare beneficiaries. CMS aims to ensure that adequate protections of information collected by QIOs are in place and, at the same time, to ensure that the quality improvement activities of these institutions and practitioners are not unnecessarily hindered by regulations. It has come to our attention that the existing regulations omit information disclosure procedures that would allow for the effective and efficient exchange of information that is an essential part of quality improvement activities. In addition, it has come to our attention that, although the QIO does not need the consent of the institution to release nonconfidential information, the existing 30-day advance notice requirement to an institution prior to releasing public information or any other nonconfidential information that identifies an institution, when an institution consents to or requests the release of information, impedes the ability of QIOs to conduct quality improvement work. If the institution requests or consents to the release of the information, the institution is already aware of the QIO's intention to disclose the nonconfidential information. Therefore, we see no reason to require the additional 30-day advance notice. Likewise, there is no reason to require a 30-day notice for practitioners who request the release of information for quality improvement activities or other permissible releases under the regulations.

B. Provisions of the May 18, 2004 Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28332), we proposed to make several changes in the regulations in Part 480 to expedite the exchange of information and minimize delays and expenditures currently required of QIOs, institutions, and practitioners as discussed below.

Existing §480.105(a) requires that a QIO must notify an identified institution of its intent to disclose nonconfidential information about the institution and provide a copy of the information at least 30 calendar days before the disclosure. Section 480.105 also includes certain notice requirements a QIO must meet before disclosing confidential information that identifies practitioners and physicians. Section 480.106 presently includes several exceptions to these notice requirements. We proposed to revise §480.106 to establish additional exceptions to the notice requirements in §480.105(a) and (b)(2). We proposed to specify that the notice requirements in §480.105(a) and (b)(2) would not apply if (1) the institution or practitioner has requested, in writing, that the QIO make the disclosure; (2) the institution or practitioner has provided written consent for the disclosure; or (3) the information is public information as defined in §480.101 and specified in §480.120.

Existing §480.133(a)(2)(iii) specifies that a QIO may disclose to any person, agency, or organization confidential information on a particular practitioner or reviewer with the consent of that practitioner or reviewer, provided that the information does not identify other individuals. In the May 18, 2004 IPPS proposed rule (69 FR 28369), we proposed to revise §480.133(a)(2)(iii) to allow for the release of information at the written request of the practitioner or reviewer, in addition to information releasable with

the consent of the practitioner or reviewer under the existing provision. Specifically, the proposed revised §480.133(a)(2)(iii) would provide that a QIO may disclose confidential information about a particular practitioner or reviewer at the written request of, or with the written consent of that practitioner or reviewer. The recipient of the information would have the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer would, under the authority of Subpart B of Part 480. In addition, we proposed a similar revision to §480.140 relating to the release of quality review study information. Specifically, we proposed to revise §480.140 by adding a new paragraph (d) (the existing paragraphs (d) and (e) would be redesignated as paragraphs (e) and (f), respectively) to provide that a QIO may disclose quality review study information with identifiers of particular practitioners or institutions at the written request of, or with the written consent of, the identified practitioner(s) or institution(s). The recipient of the information would have the same redisclosure rights and responsibilities as the requesting or consenting practitioner or institution would, under the authority of Subpart B of Part 480. (We note that we published a correction to the language for this proposal in the **Federal Register** on June 25, 2004 (69 FR 35920). In that notice, we indicated that we had inadvertently referred to a "reviewer" and a "consenting reviewer" in this provision. We should have indicated an "institution" and a "consenting institution.")

In the May 18, 2004 proposed rule, we indicated that we believed these proposed revisions would reduce the existing burden on practitioners, institutions, and QIOs and, at the same time, ensure that necessary protections on information remain in place. We also

believed that the proposed revisions would allow QIOs, institutions, and practitioners to share vital information in an effective manner and further our efforts to ensure the highest quality of care possible for Medicare beneficiaries.

C. Technical Changes

In the May 18, 2004 IPPS proposed rule (69 FR 28369), we proposed to revise the title of Part 480 under Subchapter F of Chapter IV of 42 CFR to conform it to a previous regulatory change in the name of the organization conducting medical reviews under Medicare from a peer review organization to a quality improvement organization. The proposed new title is "Part 480--Acquisition, Protection, and Disclosure of Quality Improvement Organization Information".

In a final rule published in the **Federal Register** on November 24, 1999 (64 FR 66279), we redesignated Part 476 as Part 480. However, as part of the redesignation process, we inadvertently failed to make appropriate changes to the cross-references in various sections under the redesignated Part 480. In the May 18, 2004 proposed rule, we proposed to correct those cross-references.

We received a number of public comments in support of the proposals for QIO information requirements and therefore, are adopting as final the proposals and the title change without further modification.

VIII. Policy Changes Relating to Medicare Provider Agreements for Compliance with Bloodborne Pathogens Standards, Hospital Conditions of Participation, and Fire Safety Requirements for Certain Health Care Facilities

A. Hospital Conditions of Participation for Discharge Planning

1. Background

As part of the definition of "hospital," sections 1861(e)(1) through (e)(8) of the Act set forth specific requirements that a hospital must meet to participate in the Medicare program. Section 1861(e)(9) of the Act specifies that a hospital also must meet other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in hospitals. Implementing regulations for section 1861(e) of the Act, setting forth the conditions of participation (CoPs) that a hospital must meet to participate in the Medicare program, are located in 42 CFR Part 482.

The purposes of these CoPs are to protect patient health and safety and to ensure that high quality care is furnished to all patients in Medicare-participating hospitals. In accordance with section 1864 of the Act, State survey agencies conduct surveys of hospitals to determine compliance with the Medicare CoPs, using interpretive guidelines and survey procedures found in the State Operations Manual (SOM), CMS Publication No. 7. In accordance with section 1865 of the Act and the implementing regulations at 42 CFR §§488.5(a) and 488.6, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Osteopathic Association (AOA), or other national accreditation organizations are not routinely

surveyed by States for compliance with the CoPs, but are deemed to meet most of the hospital CoPs based on their accreditation. However, all hospitals that participate in the Medicare program are required to be in compliance with the CoPs, regardless of their accreditation status. Under section 1905(a) of the Act, the hospital CoPs also apply to hospitals participating in Medicaid (§440.10(a)(3)(iii) and §482.1(a)(5)).

Under §489.10(d), a Medicare provider agreement is subject to the State survey agency's determination of whether a hospital meets the CoPs. The State survey agency makes corresponding recommendations to CMS about the hospital's certification; that is, whether the hospital has met the standards or requirements necessary to provide Medicare and Medicaid services and receives Federal and State reimbursement.

Section 4321(a) of Pub. L. 105-33 (BBA) amended section 1861(ee)(2) of the Act to require that Medicare-participating hospitals, as part of the discharge planning process, share with each patient, as appropriate, a list of available home health services through individuals and entities, including Medicare-certified home health agencies (HHAs) that participate in Medicare, serve the geographic area in which the patient resides, and request to be listed by the hospital as available. In addition, section 4321(a) prohibits hospitals from limiting or steering patients to any specific HHA or qualified provider that may provide posthospital home health services and requires hospitals to identify (in a form and manner specified by the Secretary) any HHA or other entity to whom the individual is referred in which the hospital has a disclosable financial interest consistent with section 1866(a)(1)(S) of the Act or which has a financial interest in the hospital if the patient is referred to that entity.

Congress enacted section 4321of Pub. L. 105-33 to protect patient choice and enable Medicare beneficiaries to make more informed choices about the providers from which they receive certain Medicare services. We believe that this provision was intended to address concerns that some hospitals were referring patients only to HHAs in which they had a financial interest, and that shared financial relationships were influencing referrals to other entities. Hospitals essentially have a captive patient population and, through the discharge planning process, can influence a patient's choice regarding who provides posthospitalization services.

Congress also enacted section 926 of Pub. L. 108-173 (MMA) to improve the administration of the Medicare program by protecting patient choice and enabling Medicare beneficiaries to make more informed choices about the providers from which they receive Medicare services. Section 926(a) of Pub. L. 108-173 requires the Secretary to publicly provide information that enables hospital discharge planners, Medicare beneficiaries, and the public to identify SNFs that are participating in the Medicare program. Section 926(b) of Pub. L. 108-173 amended section 1861(ee)(2)(D) of the Act to require Medicare-participating hospitals, as part of the discharge planning process, to include a discharge planning evaluation of a patient's likely need for posthospital extended care services and the availability of these services through facilities that participate in the Medicare program and that serve the geographic area in which the patient resides. The amendments to the Act made by section 926(b) of Pub. L. 108-173 apply to discharge plans made on or after a date specified by the Secretary, which may be

no later than 6 months after the Secretary provides for the availability of information required by section 926(a) of Pub. L. 108-173.

2. Implementation

We implemented the requirements of section 4321(a) of Pub. L. 105-33 relating to information on HHAs through a HCFA (now CMS) directive that was issued to the Regional Offices and State survey agencies on October 31, 1997. Enforcement has been carried out through the State agency survey and certification process. We note that even though it was not a requirement under section 4321(a) to provide currently available information on HHAs to the public (as now required under section 1861(ee)(2)(D) of the Act, as amended), we have established a "Home Health Compare" link on the CMS website, **www.medicare.gov**, that identifies HHAs that are currently participating in the Medicare or Medicaid program.

3. Provisions of the Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28196, 28333), we proposed to incorporate in our regulations under §482.43 the requirements of section 4321(a) of Pub. L. 105-33 relating to providing information on HHAs to hospital patients as part of the discharge planning process. We noted that we had previously issued a proposed rule on December 19, 1997 (62 FR 66726) to implement the provisions of section 4321(a) of Pub. L. 105-33. However, section 902 of Pub. L. 108-173 now requires us to finalize rules within 3 years after publication of the proposed rule, except under "exceptional circumstances." While it is not clear whether Congress intended this policy to apply retroactively, out of an abundance of caution, we issued a new proposed rule because of

the length of time that has elapsed since the issuance of the 1997 proposed rule. Moreover, the provisions of Pub. L. 108-173 contain information requirements for SNFs substantially similar to the ones required for HHAs. In developing the May 18, 2004 proposed rule, we took into consideration the issues raised in the public comments we received on the December 19, 1997 proposed rule relating to HHAs.

Information on SNFs related to the requirement imposed by section 926(a) of Pub. L. 108-173 is currently available to the public and can be accessed at the CMS website, **www.medicare.gov**, by clicking on the "Nursing Home Compare" link or by calling 1-800-MEDICARE (800-633-4227). Nursing Home Compare, launched in November 2002, meets the statutory requirement of section 926(a) by enabling hospital discharge planners, Medicare beneficiaries, and the public to identify the 17,000 nursing homes that participate in the Medicare or Medicaid program. Nursing Home Compare can be used to locate a nursing home by State and county, by proximity (city or zip code), or by name. In addition, Nursing Home Compare provides detailed information about the past performance of every Medicare-certified and Medicaid-certified nursing home in the country. The data on this website describe nursing home characteristics, quality measures, inspection results, and nursing staff information. The Nursing Home Compare tool received 9.3 million page views in 2003 and was the most popular tool on **www.medicare.gov**. If an interested individual does not have access to the Internet, the individual can call 1-800-MEDICARE (800-633-4227) and request a printout of the nursing homes in a designated area.

In the May 18, 2004 proposed rule, we proposed to amend the regulations at §482.43 to incorporate the provisions of section 4321(a) of Pub. L. 105-33 and section 926(b) of Pub. L. 108-173 into the hospital CoPs. Specifically, we proposed to add new paragraphs (c)(6), (c)(7), and (c)(8) to include the requirement for hospitals to provide lists of Medicare-certified HHAs and SNFs as part of the discharge planning process. We proposed that the discharge planning evaluation would be required to include a list of Medicare-certified HHAs that have requested to be placed on the list as available to the patient and that serve the geographic area in which the patient resides. We proposed to require the SNF list to include Medicare-certified SNFs located in the geographic area in which the patient requests. However, we did not propose to require that the list of Medicare-certified SNFs contain exclusively those SNFs that are located in the area in which the patient resides. Because many available Medicare-certified SNFs are not located in proximity to where the patient resides, especially in rural areas, we believe that a requirement that restricts information to those SNFs in the areas where the patient resides is too restrictive and would limit the availability of posthospital extended care services to Medicare beneficiaries.

Section 4321(a) of Pub. L. 105-33 requires listing the availability of home health services through individuals and entities. We have received inquiries regarding the identity of those individuals and entities. In the May 18, 2004 IPPS proposed rule (69 FR 28333) we proposed that, because section 1861(m) of the Act identifies home health services as "specific items or services furnished to an individual, who is under the

care of a physician, by an HHA, or by others under arrangements with an HHA," section 4321(a) is referring to Medicare-participating HHAs.

We proposed that the hospital present the list of HHAs or SNFs only to patients for whom home health care or posthospital extended care services are indicated as appropriate, as determined by the discharge planning evaluation. We do not expect that patients without a need for home health care or posthospital extended care services would receive the list. In addition, we proposed to require the hospital to document in the patient's medical record that a list of HHAs or SNFs was presented to the patient or an individual acting on the patient's behalf. Hospitals would not have to duplicate the list in the patient's medical record. The information in the medical record would serve as documentation that the requirement was met. The hospital would have the flexibility to determine exactly how and where in the patient's medical record this information would be documented.

We proposed that we would allow a hospital the flexibility to implement the requirement to present the lists in a manner that is most efficient and least burdensome in its particular setting. A hospital can simply print a list from the Home Health Compare or Nursing Home Compare site on the CMS website, **www.medicare.gov** or develop and maintain its own list of HHAs and SNFs. When the patient requires home health services, the CMS website list can be printed based on the geographic area in which the patient resides. When the patient requires posthospital extended care services, the CMS website list would be printed based on the geographic area requested by the patient. Or, in the rare instance when a hospital does not have Internet access, the hospital can call

1-800-MEDICARE (1-800-633-4227) to request a printout of a list of HHAs or SNFs in the desired geographic area. Information on this website should not be construed as an endorsement or advertisement for any particular HHA or SNF.

Under the proposed rule, if a hospital chooses to develop its own list of HHAs or SNFs, the hospital would have the flexibility of designing the format of the list. However, the list should be utilized neither as a recommendation nor endorsement by the hospital of the quality of care of any particular HHA or SNF. If a HHA or SNF does not meet all of the criteria for inclusion on the list (Medicare-certified and is located in the geographic area in which the patient resides or in the geographic area requested by the patient), we did not propose to require the hospital to place that HHA or SNF on the list. In addition, in accordance with the provisions of the Act, we proposed that HHAs must request to be listed by the hospital as available. We also proposed that the list must be legible and current (updated at least annually), and that the listed information be shared with the patient or an individual acting on the patient's behalf at least once during the discharge planning process. However, we indicated that, under the proposal, information regarding the availability of HHAs or SNFs may need to be presented more than once during the discharge planning process to meet the patient's need for additional information or as the patient's needs and condition change.

In the May 18, 2004 proposed rule (69 FR 28333), we proposed to require that, as part of the discharge planning process, the hospital must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital services and must, when possible, respect patient and family preferences

when they are expressed (proposed §482.43(c)(7)). In addition, the hospital may not use the discharge plan to specify or otherwise limit the patient's choice of qualified providers that may provide home health care or posthospital extended care services. The intent of the proposed provision was to provide the patient with the freedom of choice to determine which HHA or SNF will provide care in accordance with section 1802 of the Act, which states that beneficiaries may obtain health services from any Medicare-participating provider.

Finally, we proposed to require the hospital to identify in each discharge plan those HHAs or SNFs to which the patient is referred that the hospital has a disclosable financial interest or HHAs or SNFs that have a financial interest in the hospital (proposed §482.43(c)(8)). For the purposes of implementing section 4321(a) of Pub. L. 105-33, we proposed to define a disclosable "financial interest" as any financial interest that a hospital is required to report according to the provider enrollment process, which is governed by section 1124 of the Act and implementing regulations located in 42 CFR Part 420, Subpart C, and accompanying manual provisions. If a hospital refers patients about to be discharged and in need of posthospital services only to entities it owns or controls, the hospital would be infringing on the rights of the patient to choose the facility he or she would like to go to for services. The proposed disclosable financial interest requirement is an effort to increase the beneficiary’s awareness of the actual or potential financial incentives for a hospital as a result of the referral. To allow hospitals the flexibility of determining how these financial interests are disclosed to the patient, we did not propose to require a specific form or manner in which the hospital must disclose

financial interest. The hospital could simply highlight or otherwise identify those entities in which a financial interest exists directly on the HHA and SNF lists. Or, the hospital could choose to maintain a separate list of those entities in which a financial interest exists.

In the May 18, 2004 IPS proposed rule (69 FR 28335), we indicated that hospitals and managed care organizations (MCOs) have expressed concern as to whether the change made by section 4321(a) of Pub. L. 105-33 was intended to apply to patients in managed care plans. MCO members are limited as to what services they may obtain from sources other than through the MCO. We believe that providing MCO members with a standardized list of all HHAs or SNFs in the requested geographic area could be misleading and potentially financially harmful because MCO enrollees may be liable for services that they obtain from providers other than the MCO, and patients may interpret a list of HHAs or SNFs that are not available to them under their health plan to mean that they are authorized by the MCO. This does not mean that Medicare MCO members in particular are denied the freedom of choice they are entitled to under section 1802 of the Act. Medicare beneficiaries exercise their freedom of choice when they voluntarily enroll in the MCO and agree to adhere to the plan's coverage provisions.

The list provided to MCO patients should include available and accessible HHAs or SNFs in a network of the patient's MCO. Hospitals also have the option, in the course of discussing discharge planning with patients, to determine whether the beneficiary has agreed to excluded services or benefits or coverage limitations through enrollment in a

MCO. If this is the case, the hospital could inform the patient of the potential consequences of going outside the plan for services.

We also indicated in the proposed rule that we had received many inquiries about how the requirements contained in section 4321(a) of Pub. L. 105-33 are monitored and enforced. Once codified in the hospital CoPs, a hospital's obligations under both section 4321(a) of Pub. L. 105-33 and section 926 (b) of Pub. L. 108-173 would be monitored as part of the hospital survey and certification process. Anyone aware of instances in which patients were inappropriately influenced or steered toward a particular HHA or SNF in a way that violated the regulation would have the opportunity to file a complaint with the State survey agency. The State survey agency would then investigate and follow up with the complainant. Noncompliance with the hospital CoPs could result in a hospital losing its ability to participate in the Medicare program.

Requiring hospitals to provide a list of Medicare-certified HHAs or SNFs would provide patients with more options and assist them in making informed decisions about the providers from which they receive Medicare services. Specifically, the intent of the proposed modifications to the discharge planning CoPs was to provide the patient with the freedom of choice to determine which HHA or SNF available in the geographic area in which the patient resides or the geographic area requested by the patient, would provide them care in accordance with section 1802 of the Act, which states that beneficiaries may obtain health services from any Medicare-participating provider.

We received numerous comments from providers and provider organizations regarding the hospital CoP for discharge planning. Commenters supported our intent to

protect patient choice and enable patients and their families to make more informed decisions. Commenters focused on various operational issues, such as format and scope of HHA and SNF lists to be provided, the process for updating lists, the feasibility of providing SNF information based on geographic location, a hospital's responsibility in providing information to Medicare managed care enrollees, and expanding the requirement beyond HHAs and SNFs.

Comment: Commenters requested that the HHAs and SNFs be listed alphabetically on different lists according to provider type. In addition, the commenters requested that the list include the services that the HHA offers (for example, skilled nursing, physical therapy, occupational therapy, speech therapy, clinical social work, mental health nursing, and home health aides). Commenters stated that including the list of services that the HHA offers would make it clear to patients which agency they can choose according to their needs and the services the agency provides. Commenters stated that hospital lists are often confusing and contain numerous types of providers and services offered in a single document. Another commenter stated that hospitals should be required to provide HHAs with notice that the list is being updated, and should provide HHAs with a copy of the list once compiled to ensure that the HHAs are listed and the information provided is accurate.

Response: Hospitals have the flexibility to either print a list of HHAs or SNFs from the CMS website or develop and maintain their own lists. Hospitals that choose to develop and maintain their own lists have the flexibility to determine the format. We agree that the list should be user friendly and that information regarding HHAs and SNFs

should not be co-mingled within the same list. However, as long as HHA information is categorized separately from SNF information, the two lists could be included in the same document. We expect hospital discharge planners to be able to assist patients in identifying the HHAs and SNFs appropriate to fit the patient's needs. This information is available on the CMS website and can be included on the HHA list at the discretion of each hospital. We do not believe it is necessary to prescribe a process for hospitals to update their lists. We expect hospitals to update their lists at least annually. Hospitals have the flexibility to develop their own process for this update. Information on the CMS website is updated as new information becomes available. We believe the commenters' concerns are addressed by the CMS website. We encourage hospitals to use the Home Health and Nursing Home Compare websites to access information.

We believe that utilization of the CMS websites will be the most efficient and least burdensome way for many hospitals to implement these requirements.

Comment: Several commenters stated that requiring hospitals to provide lists of Medicare certified SNFs located in the geographic area chosen by the patient updating the list for frequent changes, and identifying SNFs with which disclosable financial interests exist would impose an additional, unnecessary, and unreasonable burden on hospital discharge planners. They further stated that current regulations already require hospitals to provide choices to Medicare beneficiaries for posthospital services. Commenters stated that the proposed rule acknowledges "hospitals currently access this information as an essential component of the discharge planning process." Commenters also stated that the equipment required for Internet access, the labor involved in

telephoning an agency with limited hours of operation, as well as actual time to obtain information telephonically, add to the costs of providing care.

Response: In this final rule, we are implementing a statutory requirement contained in section 926 of Pub. L. 108-173. Congress enacted this legislation to improve the administration of the Medicare program by protecting patient choice and enabling Medicare beneficiaries to make more informed decisions about the providers from which they receive Medicare services. Hospitals have the flexibility to implement this requirement in a way that makes the most sense for them. One option would be for a hospital to print out or call the 800 number to request a list of SNFs located in the selected geographic areas or entire state that the hospital serves on a regular basis, for example, annually. It is not necessary to generate a new, separate list for every patient. If Internet access is not available to discharge planners or calling the 1-800-MEDICARE (800-663-4227) are both determined to be unfeasible, the hospitals will be free to develop and maintain their own lists. We expect hospitals to keep the lists current. Hospitals have the flexibility in determining how and how frequently they update their lists. The intent is to protect patient choice and provide patients and their families with the information necessary to make informed decisions. As the commenters pointed out, we believe that discharge planners currently access this information as an essential component of the discharge planning process. Therefore, we believe the additional burden is minimal.

Comment: A commenter expressed agreement with our proposal that SNF information should be presented based on the geographic area requested by the patient.

Commenters further stated that the same requirement should be imposed on hospitals with respect to HHAs. The commenter recommended deleting the reference to serving "the geographic area (as defined by the HHA)" and deleting the requirement that "HHAs must request to be listed by the hospital as available."

Response: Section 4321(a) of the BBA specifically requires that HHAs serving the area in which the patient resides request to be listed by the hospital as available. We believe the HHA is in the best position to identify its service area and, presumably, would not misrepresent its service area by requesting to be listed for an area they do not serve. Section 926 of Pub. L. 108-173 does not contain a similar requirement for SNFs.

Comment: A commenter stated that her hospital currently provides a list of HHAs and indicates for patients any agencies in which the hospital has a financial interest. The Commenters states that this process works well in supporting patient choice. However, two commenters stated that expanding this requirement to SNFs does not work because nursing home placement is primarily driven by bed availability and special care accommodations; location is secondary. The commenter stated that patients who are given a list of nursing homes in a 10-mile radius will be overwhelmed by the number of nursing homes and confused as to where to begin. The commenter further stated that such a list would only create expectations that the patient can go to any of these facilities and that they truly do have options when in reality options may be extremely limited or nonexistent due to lack of available of beds. The commenter supports a process that communicates to the patient what research was done in checking bed availability and gives the patient a list of true options for choice if options do in fact

exist. The commenters also suggested that SNF quality information might be helpful if options are limited due to bed availability.

Response: We appreciate the commenters' support of the HHA list and patient choice. We recognize that bed availability is a major issue in terms of SNF placement. Our intent is to provide patients with real options. We would not expect that the patient be given an exhaustive list of SNFs with no available beds. The intent is to provide patients and their families with information in order to make informed decisions. As the discharge planner identifies which SNFs have available beds, this information should be shared with the patient and patient's family. The nursing home compare website currently provides nursing home quality information. A hospital may elect to share this quality information with the patient and patient's family or simply direct them to this website as a resource.

Comment: One commenters suggested delaying implementation of the SNF list as a formal requirement until a better system for identifying SNF bed availability and special care accommodations could be developed. The commenters made the following recommendations: (1) update the Nursing Home Compare tool to include a section on special care accommodations available (for example, skilled, nonskilled, residential, Alzheimer, and availability of specialized ancillary staff), as well as the number of unskilled beds, Medicaid designated beds/specialty beds by category, to facilitate planning efforts; (2) amend the Home Health Compare "search" function to include the ability to identify agencies based on the main service area of the agency versus the geographic location of the agency; (3) eliminate the sorting of HHAs by zip code; (4)

revise the print format to fit 8 ½ x 11 size paper; and (5) develop State or regional databases that will facilitate patient placement in available SNF beds. The commenters also requested that future policy changes be released in notices in addition to the **Federal Register** to facilitate more comments and recommendations.

Response: Delaying implementation of this requirement is not an option. Section 926 of Pub. L 108-173 requires that information regarding SNFs that participate in the Medicare program be available on hospital discharge plans within 6 months of enactment of the law. Revision of the content and format of the Home Health and Nursing Home Compare websites is beyond the scope of this rule. However, we have forwarded the commenters' recommendations to appropriate agency staff for consideration. We alert the public to notices published in the **Federal Register** in a variety of ways. These ways include several of listings that may be accessed on the CMS website at **www.cms.hhs.gov** (for example, the Quarterly Provider Update and current publications and press releases). In addition, the public may register at CMS website to receive email updates. Public notice is also provided at the monthly Open Door Forums.

Comment: One commenters expressed concern regarding the identification and disclosure of SNF providers that accept Medicare+Choice because current tools only indicate Medicare and Medicaid participation. Another commenter requested that we modify the proposed regulations to explicitly indicate the responsibilities of hospitals with regard to managed care organization (MCO) enrollees.

Response: We believe that identifying MCO participating HHAs or SNFs is currently part of a hospital's discharge planning process. We also believe that providing

MCO members with a standardized list of all HHAs or SNFs that does not identify those that are authorized by the MCO could be misleading. Patients may interpret this type of list to mean that all of the HHAs or SNFs listed are authorized by the MCO. It could be potentially financially harmful because MCO enrollees may be liable for services that they obtain from providers other than the MCO. The list provided to MCO patients should include all available and accessible HHAs or SNFs as well as those authorized by a patient's MCO. The hospital could simply identify these MCO authorized HHAs or SNFs for the patient by highlighting them on the list. The patient has the freedom to choose a HHA or SNF not authorized by the MCO. If the patient chooses a HHA or SNF not authorized by the MCO, the hospital should inform the patient of the potential consequences of going outside the plan for services. Therefore, we are adding §482.43(c)(6)(ii) to ensure that patients enrolled in MCOs are provided with listings that identify authorized HHAs or SNFs.

Comment: Commenters recommended that the lists be made available to all patients who potentially require any type of posthospital services, not just those determined by the discharge planning evaluation to require HHA or SNF services. Another commenter stated that all beneficiaries should be provided with written information advising them that they may be entitled to home health services.

Response: We note that the language of the statute only requires that lists of HHAs and SNFs be provided to the appropriate patients. In addition, we believe it would be unnecessarily burdensome to require that hospitals develop and provide a list of all posthospital services to their patients. Hospitals are free to provide all patients with

written information advising them that they may be entitled to home health services. However, we do not believe that the intent of the statute is to require that this information be provided to all patients.

Comment: A commenter suggested that hospitals be required to direct the patients and their family to the Home Health Compare website. The commenter stated that the website provides both a useful tool for locating area specific HHAs while providing a means for patients to conduct a comparative review.

Response: We appreciate the commenter's support of the Home Health Compare website. Hospitals are free to direct patients and their families to this website as part of their discharge planning process. However, we believe requiring hospitals to direct patients and their families to the Home Health Compare website is not appropriate because some patients and their families may not have Internet access.

Comment: A commenter requested that the words "when possible" be removed from §482.43(c)(7). The commenter stated that in her experience hospitals would just say that they could not reach the agency and not even call the agency in question. Two commenters suggested that the hospital be required to document when they called and to whom the discharge planner spoke. The commenter requested the following language be added: "The hospital discharge planner or anyone else from the hospital may not recommend that a patient use a particular agency or tell the patient that they have to use the hospital agency because they are in that hospital." Lastly, the commenter requested that the word "respect" be changed to "honor."

Response: We understand the commenters' concern that hospitals may steer patients to certain HHAs. However, we believe there are legitimate circumstances when it may not be possible to respect patient and family preferences. For example, a preferred HHA or SNF may not be able to accommodate the patient's needs within the required timeframe or a preferred HHA may be unable to provide the required services. We believe a requirement to include documentation of these circumstances would create an unnecessary burden for hospitals. Section 482.43(c)(7) stipulates that the hospital must not exclude qualified providers that are available to the patient. Steering a patient to a particular agency or limiting access to an agency constitutes excluding qualified providers. Such practices would be a violation of this regulatory provision. We note that the meanings of "respect" and "honor" are similar, and, therefore, we are retaining the word "respect".

Comment: One commenter requested that we use the statutory language in section 1861(ee)(2)(H) of the Act, requiring that plans "not specify or otherwise limit the qualified provider which may provide posthospital home health services." The commenter stated that it might be useful to include within the rule the particular prohibition set out in the statute.

Response: We agree with the commenter and are revising §482.83(c)(7) to reflect this change.

Comment: Commenters recommended that the regulation be modified to include hospice among the posthospital care providers where a list of hospices is made available to the patient, along with the other protections on the patient's freedom of choice.

Another commenter stated that hospitals should be required to provide lists of all providers and services available to patients upon discharge.

Response: Section 1861(ee) of the Act requires hospitals to have a discharge planning process that meets certain enumerated requirements. Included in that statutory provision is the requirement that the discharge planning evaluation incorporate an evaluation of the patient's likely need for appropriate posthospital services and the availability of those services. Section 4321 of the BBA amended the discharge planning requirements to require that the discharge planning evaluation indicate the availability of home health services provided by individuals or entities that participate in the Medicare program. Specifically, section 4321(a) of the BBA provided that the discharge planning evaluation include an evaluation of the patient's likely need for posthospital services and the availability of those services; "including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available." We have interpreted this provision to require that hospitals need only indicate the availability of home health services provided by HHAs that request to be listed in the discharge plan, as opposed to the universe of individuals and entities that participate in the program. We believe that our interpretation is consistent with the BBA provision. As noted previously, section 4321(a) requires that hospitals, in their discharge planning evaluation, provide a listing regarding the "availability of home health services." Section 1861(m) of the Act defines home health services as services "furnished by a home health agency" (as opposed to other posthospital entities). Section 926 of Pub. L. 108-173

further amended 1861(ee) to include information regarding skilled nursing facilities that participate in the Medicare program. Therefore, in accordance with the Act, we interpret these provisions as not applying to individuals or entities that provide posthospital services other than HHAs and SNFs. However, we expect the discharge planner to facilitate patient choice in any posthospital extended care services as part of the discharge planning process even though the statute does not require a specific list beyond HHAs and SNFs. We are revising §482.43(c)(7) to clarify our policy regarding patient choice in posthospital care services.

Comment: Commenters stated that CMS should provide authorization to state surveyors to find a violation of the hospital CoPs if the overall effect of a discharge/referral practice evidences a clear intent to subvert or violate the purpose of section 4321 of the BBA. One commenter also stated that CMS should specify that exclusion of a hospital's own HHA from the list does not permit the hospital to "steer" a beneficiary to that agency, and that it is improper for a hospital to limit inclusion on the list to accredited HHAs. Another commenter requested that CMS address the issue of whether review of a patient's hospital record by an HHA that the patient has not selected violates the HIPAA privacy requirements.

Response: Compliance with the hospital CoPs is monitored by the State survey agencies as part of the survey and certification process or, in the case of accredited hospitals, by JCAHO, the AOA or other CMS approved accreditation organizations. Noncompliance with the regulations contained within the hospital CoPs can result in a hospital losing its status as a Medicare participating provider. Anyone aware of instances

where patients are being inappropriately influenced or steered toward a particular HHA, SNF or other entity in which the hospital or individual has a financial interest can file a complaint with the appropriate State survey agency. The list provided to the patient must include certified HHAs, both accredited and nonaccredited, to meet the intent of the statute.

In addition, disclosing a patient's hospital record to an HHA that the patient has not selected would be a violation of HIPAA, Pub. L. 104-191. Regulations implementing HIPAA are published in 45 CFR Parts 160 and 164.

Comment: One commenter recommended that details discussed in the preamble be included as regulation text. These details include: use of the Home Health Compare website; hospitals that create their own lists should include, at a minimum, those providers who request inclusion on the list; and hospital lists should be updated annually.

Response: A hospital has the flexibility to implement the requirements in a manner that is most efficient and least burdensome in its particular setting. Hospitals may choose to develop their own list of HHAs or utilize the Home Health Compare website. We do not believe reference to the Home Health Compare website needs to be in the regulation as hospitals are free to develop their own list. The regulation requires that the hospital list include HHAs that: participate in the Medicare program; serve the geographic area (as defined by the HHA) in which the patient resides; and request to be listed by the hospital as available. In terms of frequency of updating the list, we have decided to be less prescriptive and not require the hospital to update the list annually as discussed in the preamble of the proposed rule. Instead, we expect hospitals to keep their

lists current. This provides hospitals the flexibility to determine how often it is necessary to update their lists.

Comment: One commenter stated that HHAs new to the Medicare program are not listed on the Home Health Compare website until they have submitted OASIS data for at least 6 months. The commenter also stated that when a search is conducted using zip code or county, Home Health Compare only brings up agencies who have served a patient within that zip code or county within the past year. The commenter requested that Medicare-certified HHAs be allowed to request inclusion on the hospital list at any time.

Response: We appreciate the points made by the commenter. However, the regulation does not prescribe the timeframe in which a HHA can request inclusion on a hospital list. The hospital has the freedom to determine a timeframe if they determine that a timeframe is necessary.

Comment: One commenter requested that hospital staff, other than discharge planners, not discuss particular posthospital providers with patients before the patient has selected a provider.

Response: We agree that it may be confusing to patients if hospital staff other than those involved in the discharge planning process discuss posthospital providers with patients. However, discharge planning is a multidisciplinary process that includes staff beyond the discharge planner. The intent of this regulation is to support the patient's freedom to choose. No one on the hospital staff may specify or otherwise limit the qualified providers that are available to the patient.

Comment: One commenter stated that financial interests should be disclosed to patients before exercising their right to choose a HHA, not after the patient is referred.

Response: We agree that financial interests should be disclosed to patients before patients exercise their right to choose a HHA. We do not interpret the term "referred" to mean that a patient has made a decision and has chosen a particular HHA. We interpret this to mean that a patient is referred to a list of HHAs. The discharge plan must identify those HHAs in which a disclosable financial interest exists. HHAs in which a disclosable financial interest exists can simply be highlighted in some fashion on the list.

Comment: One commenter stated that the discharge planning process should provide the same information to all patients regardless of payer. Another commenter requested clarification as to whether or not this policy is intended to apply to both PPS hospitals and CAHs.

Response: The hospital CoPs apply to all patients in Medicare-and Medicaid-participating hospitals regardless of payer. We expect all patients to receive the same information. The hospital CoPs are not applicable to CAHs.

Comment: One commenter stated that, if hospitals are creating their own lists, there are no standards for the process that HHAs are to follow to ensure placement on the hospital listing.

Response: The standards for ensuring placement on the hospital list are outlined in the regulation. The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the

case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

Comment: One commenter urged CMS to move forward with implementing the remainder of the BBA provisions at sections 4321(b) and (c).

Response: In the November 22, 2002 **Federal Register** (67 FR 70373), we published a proposed rule entitled, "Medicare Program: Nondiscrimination in Posthospital Referral to Home Health Agencies and Other Entities" (CMS-1223-P), which specified our proposal to implement sections 4321(b) and (c) of the BBA. The final rule is currently in the agency clearance process.

Based on public comments, we are making two revisions to the regulations text in this final rule. In §482.43, we are adding a new paragraph (c)(6)(ii) that states, "For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations."

In addition, we are revising §482.43(c)(7) to read, "The hospital, as part of the discharge planning process, must inform the patient or patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed" and "The hospital must not specify or otherwise limit the qualified providers that are available to the patient."

The remainder of the proposed provisions is adopted as final without change.

B. Compliance with Bloodborne Pathogens Standards

1. Background

Section 1866(a)(1) of the Act sets forth provider agreement requirements that Medicare-participating hospitals must meet. Implementing regulations for these requirements are set forth at 42 CFR 489.20.

Section 947 of Pub. L. 108-173 amended section 1866(a)(1) of the Act to require that, by July 1, 2004, hospitals not otherwise subject to the Occupational Safety and Health Act (OSHA) (or a State occupational safety and health plan that is approved under section 18(b) of that Act) must comply with the OSHA bloodborne pathogens (BBP) standards at 29 CFR 1910.1030 as part of their Medicare provider agreements. These OSHA standards can be found on OSHA's website at **http://www.osha.gov/SLTC/bloodbornepathogens/**. Section 947 of Pub. L 108-173, which applies to hospitals participating in Medicare as of July l, 2004, was enacted to ensure that all hospital employees who may come into contact with human blood or other potentially infectious materials in the course of their duties are provided proper protection from bloodborne pathogens. This amendment further provides that a hospital that fails to comply with OSHA's BBP standards may be subject to a civil money penalty. The civil money penalty will be imposed and collected in the same manner that civil money penalties are imposed and collected under 29 U.S.C. section 666 and section 1128A(a) of the Act. However, failure to comply with the BBP standards will not lead to termination of a hospital's provider agreement.

Currently, most hospitals are subject either to the OSHA BBP standards or to other BBP standards (generally, State standards) that meet or exceed the OSHA standards. However, non-Federal public hospitals located in States that do not have their own BBP standards are not subject to OSHA standards, including the OSHA BBP standards. Twenty-six States and the District of Columbia, and Guam do not have their own BBP standards under an OSHA-approved State plan. Therefore, an estimated 600,000 employees of such non-federal public hospitals located in those 26 States, the District of Columbia, and Guam are not afforded the same protections from BBPs as employees of all other hospitals in the United States. The States and territories that would be affected by the change made by section 947 of Pub. L. 108-173 are Alabama, Arkansas, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Kansas, Louisiana, Maine, Massachusetts, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, West Virginia, Wisconsin, the District of Columbia, the Virgin Islands, and Guam.

2. Provisions of the Proposed Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28196, 28372), we proposed to incorporate the provisions of Pub. L. 108-173 in §489.20 of the Medicare regulations governing provider agreements by adding a new paragraph (t). In paragraph (t), we proposed that hospitals not otherwise subject to the OSHA BBP standards must comply with the OSHA BBP standards at 29 CFR 1910.1030 as part of their Medicare provider agreement. We proposed to further specify that if a hospital fails to comply with OSHA's BBP standards, the hospital may be subject to a civil money penalty. The civil

money penalty would be imposed and collected in the same manner that civil money penalties are imposed and collected under 29 U.S.C. 666 and section 1128A(a) of the Act. However, as we noted previously, failure to comply with the BBP standards would not lead to termination of a hospital's provider agreement. In addition, we proposed to refer in the proposed provision to the Federal Civil Penalties Inflation Adjustment Act. This reference was intended to alert the reader that the civil money penalty amounts determined under 29 U.S.C. 666 and section 1128A(a) of the Act may, under the Federal Civil Penalties Inflation Adjustment Act, be increased to adjust for inflation.

We did not receive any timely public comments in response to the section in the May 18, 2004 proposed rule regarding implementation of OSHA's Bloodborne Pathogens regulations for hospitals. Therefore, we are finalizing the proposed bloodborne pathogens for hospitals regulatory provisions without modification.

C. Fire Safety Requirements for Certain Health Care Facilities

1. Background

On January 10, 2003, we published a final rule in the **Federal Register** (68 FR 1374) that adopted the 2000 edition of the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA) as the fire safety requirements (with specified exceptions) that we are applying to the following types of providers participating in the Medicare and Medicaid programs: long-term care facilities, hospitals, intermediate care facilities for the mentally retarded (ICF/MRs), ambulatory surgical centers (ASCs), hospices that provide inpatient services, religious nonmedical health care institutions, CAHs, and Programs of All-Inclusive Care for the Elderly (PACE).

In addition to adopting the 2000 edition of the LSC, we stated our intent to delete references to all previous editions of the LSC. However, as a result of a technical error, the reference to previous editions of the LSC in §483.70(a)(1) of the regulations for long-term care facilities was not deleted. Allowing long-term care facilities to comply with the 1967, 1973, and 1981 editions of the LSC would not adequately protect long-term care facility patients from the threat of fire and other emergencies. These editions do not recognize newer technology, nor the advances in fire safety that have been developed in the ensuing years. In addition, the existing conflicting regulatory language is confusing and contrary to the best interests of long-term care facilities and their patients. Therefore, in the May 18, 2004 IPPS proposed rule (69 FR 28196, 28371), we proposed to correct this technical error. We did not propose to make any substantive policy change.

In the January 10, 2003 final rule, we also specified that we were not adopting the provisions of Chapter 19.3.6.3.2, exception number 2 of the LSC regarding the use of roller latches for application to religious nonmedical health care institutions, hospices, hospitals, long-term care facilities, PACE programs, ICF/MRs and CAHs. We prohibit the use of roller latches in existing and new buildings, except for ASCs under Chapter 20 and Chapter 21 of the LSC, and provide for the replacement of existing roller latches, phased in over a 3-year period beginning March 11, 2003. We indicated that allowing health care facilities to continue using roller latches would not adequately protect patients in those facilities. Through fire investigations, roller latches have proven to be an unreliable door latching mechanism requiring extensive on-going maintenance to operate properly. Many roller latches in fire situations failed to provide adequate protection to

patients in their room during an emergency. Roller latches that are not maintained pose a threat to the health and safety of patients and staff. We added that we had found through our online survey, certification, and reporting (OSCAR) system data that doors that include roller latches are consistently one of our most cited deficiencies. In fact, in SNFs, roller latches in corridor doors are consistently the number one cited deficiency under the life safety requirements.

We learned that the language regarding the date when these facilities must be in compliance with the prohibition on the use of roller latches may be misinterpreted and needs to be clarified. Therefore, in the May 18, 2004 proposed rule, we proposed to clarify our intent by revising the regulations as discussed under section VIII.C.2. of this preamble. We did not propose to make any substantive policy changes.

Under our proposal, the flexibility of the January 10, 2003 final rule would remain the same. The Secretary has broad authority to grant waivers to facilities under section 1819(d)(2)(B) and section 1919(d)(2)(B) of the Act. The proposed amendments would continue to allow the Secretary to grant waivers on a case-by-case basis if the safety of the patients would not be compromised and if specific provisions of the LSC would result in unreasonable hardship on the provider. The Secretary also may accept a State's fire and safety code instead of the LSC if the State's fire and safety code adequately protects patients. Further, the NFPA's Fire Safety Evaluation System (FSES), an equivalency system, provides alternatives to meeting various provisions of the LSC, thereby achieving the same level of fire protection as the LSC.

2. Proposed Changes to the Regulations

In the May 18, 2004 IPPS proposed rule (69 FR 28337), we proposed to revise §483.70(a) to delete references to the 1967, 1973, and 1981 editions of the LSC. We also proposed to revise the following regulations applicable to the specified facilities to clarify that the facility must be in compliance with Chapter 19.2.9, Emergency Lighting, beginning March 13, 2006. In addition, we proposed to also specify that, beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 (concerning roller latches), does not apply to the facility.

a. For religious nonmedical health care institutions: §403.744(a) and (c).

b. For hospices, §418.100(d)(1), (d)(4), and new (d)(5).

c. For PACE programs, §460.72(b)(1)(i), ((b)(3), and new (b)(4).

d. For hospitals, §482.41(b).

e. For long-term care facilities, §483.70(a).

f. For ICF/MRs, §483.470(j).

g. For CAHs, §485.623(d)(1), (d)(5), and new (d)(6).

We did not receive any timely public comments in response to the section in the May 18, 2004 proposed rule regarding changes to the Life Safety Code regulations for religious nonmedical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, long-term care facilities, ICFs/MR, and CAHs. Therefore, we are adopting as final, without modification, the proposed changes to the LSC regulations.

IX. MedPAC Recommendations

We are required by section 1886(e)(4)(B) of the Act to respond to MedPAC's IPPS recommendations in our annual IPPS rules. We have reviewed MedPAC's March 1, 2004 "Report to the Congress: Medicare Payment Policy" and have given it careful consideration in conjunction with the policies set forth in this document. For further information relating specifically to the MedPAC report or to obtain a copy of the report, contact MedPAC at (202) 653-7220, or visit MedPAC's website at: **www.medpac.gov**.

We note that MedPAC, in its March 1, 2004 report, included only one recommendation concerning Medicare inpatient hospital payment policies. MedPAC's Recommendation 3A-1 states that Congress should increase payment rates for the IPPS by the projected rate of increase in the hospital market basket for FY 2005. We note that section 501(a)(3) of Pub. L. 108-173 requires that the payment rates for the IPPS be increased by the market basket percentage increase for all hospitals during FYs 2005, 2006, and 2007. However, section 501(a) also provides for reducing the update by 0.4 percentage points for any hospital that fails to submit data on a list of 10 quality indicators. We discuss this recommendation further in Appendix B of this final rule in the context of our recommendation concerning the update factor for inpatient hospital operating costs and for hospitals and hospital distinct-part units excluded from the IPPS.

X. Other Required Information

A. Requests for Data from the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access

to raw data on an expedited basis. Generally, the data are available in computer tape or cartridge format; however, some files are available on diskette as well as on the Internet at **http://www.hcfa.gov/stats/pufiles.htm.** In the May 18, 2004 proposed rule, we published a list of data files that are available for purchase from CMS or that may be downloaded from the Internet free of charge (68 FR 28337 through 28339).